PTO/SB/64 (09-04) (AW 10/2004)
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PETITION FOR REVIVAL OF AN APPLICATION FOR PATENT ABANDONED UNINTENTIONALLY UNDER 37 CFR 1.137(b)

Docket Number (Optional): BSI-430US8

First named inventor: Leonard Pinchuk
Art Unit: 3738
Application No.: 09/657,041
Examiner: _____
Filed: 09/05/2000
Title: EXPANDABLE SUPPORTIVE BRANCHED ENDOLUMINAL GRAFTS

Attention: Office of Petitions
Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
Fax: (703) 872-9306

NOTE: If information or assistance is needed in completing this form, please contact Petitions Information at (703)305-9282.

The above-identified application became abandoned for failure to file a timely and proper reply to a notice or action by the United States Patent and Trademark Office. The date of abandonment is the day after the expiration date of the period set for reply in the Office notice or action plus any extensions of time actually obtained.

APPLICANT HEREBY PETITIONS FOR REVIVAL OF THIS APPLICATION

NOTE: A grantable petition requires the following items:
(1) Petition fee;
(2) Reply and/or issue fee;
(3) Terminal disclaimer with disclaimer fee - required for all utility and plant applications filed before June 8, 1995; and for all design applications; and
(4) Statement that the entire delay was unintentional.

1. Petition fee
☐ Small entity - fee $_____ (37 CFR 1.17(m)). Applicant claims small entity status. See 37 CFR 1.27.
☒ Other than small entity - fee $1500.00 (37 CFR 1.17(m))

2. Reply and/or fee

A. The reply and/or fee to the above-noted Office action in the form of Petition for Revival of an Application for Patent ABandoned Unintentionally Under 37 CFR 1.137(b) and Declaration Pursuant to 37 CFR 1.47(a) (identify type of reply):
☐ has been filed previously on _____ .
☒ is enclosed herewith.

B. The issue fee and publication fee (if applicable) of $ _____
☐ has been paid previously on _____ .
☐ is enclosed herewith.

3. Terminal disclaimer with disclaimer fee

☒ Since this utility/plant application was filed on or after June 8, 1995, no terminal disclaimer is required.

☐ A terminal disclaimer (and disclaimer fee (37 CFR 1.20(d)) of $_____ for a small entity or $_____ for other than a small entity) disclaiming the required period of time is enclosed herewith (see PTO/SB/63).

4. STATEMENT: The entire delay in filing the required reply from the due date for the required reply until the filing of a grantable petition under 37 CFR 1.137(b) was unintentional. [NOTE: The United States Patent and Trademark Office may require additional information if there is a question as to whether either the abandonment or the delay in filing a petition under 37 CFR 1.137(b) was unintentional (MPEP 711.03(c), subsections (III)(C) and (D))].

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

Signature — 1/5/2005 Date

Jonathan H. Spadt
Typed or Printed Name

45,122
Registration Number, if applicable

P.O. Box 980
Address

610-407-0700
Telephone Number

Valley Forge, PA 19482-0980
Address

Enclosures: ☒ Fee Payment

☒ Reply, including attachments

☐ Terminal Disclaimer Form

☐ Additional sheets containing statements establishing unintentional delay

☐ Other: _____

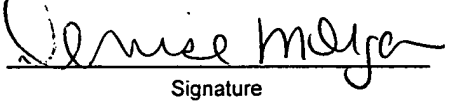
CERTIFICATE OF MAILING OR TRANSMISSION [37 CFR 1.8(a)]

I hereby certify that this correspondence is being:

☒ deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to **Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

☐ transmitted by facsimile on the date shown below to the United States Patent and Trademark Office at (703) 872-9306.

1/5/2005
Date



Signature

Denise Morgan
Typed or printed name of person signing certificate

PTO/SB/21 (05-03) (AW 07-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission 7 + attachments

Application Number	09/657,041
Filing Date	9/5/2000
First Named Inventor	Leonard Pinchuk et al.
Art Unit	3731
Examiner Name	Michael H. Thaler
Attorney Docket No.	BSI-430US8

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/Declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Response to Missing Parts/ Incomplete Application
  - ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation, Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
- ☐ After Allowance Communication to Group
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to Group **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☒ Other Enclosure(s) (please identify below): 2 pg. Petition for Revival of An Application for Patent Abandoned Unintentionally Under 37 CFR 1.137(b); 3 pg. Declaration Pursuant to 37 C.F.R. 1.147(a), including attachments; 1 pg. credit card payment form

Remarks:

SIGNATURE OF APPLICANT, ATTORNEY OR AGENT

Firm or Individual	Jonathan H. Spadt	*Registration No. (Attorney/Agent)*	45,122
Signature			
Date	1/5/2005		

CERTIFICATE OF TRANSMISSION / MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this date: 1/5/2005

Name (Print/Type)	Denise Morgan		
Signature		*Date*	1/5/2005

DECLARATION PURSUANT TO 37 C.F.R. § 1.47(a)

This Declaration is being made in accordance with 35 U.S.C. § 116, 37 C.F.R. § 1.47(a) and M.P.E.P. 409.03 *et seq*. because inventor Rysler Alcime cannot be reached after diligent effort, or because he refuses to sign. The facts as set forth below support the applicant's position that one of these two situations exists. The applicants ask, therefore, that the captioned Reissue Application proceed in the name of all three named inventors listed on the Supplemental Reissue Application Declaration attached hereto. What follows is a recitation of facts supporting this request made by the Attorney of Record in the captioned case.

This statement is being made by the available person having first-hand knowledge of the facts recited therein.

IDENTIFICATION OF PERSON MAKING THIS STATEMENT OF FACTS

Jonathan H. Spadt, Esquire
Attorney of Record
U.S. Serial No. 09/657,041

1. On January 5, 1999, U.S. Patent No. 5,855,598 (the '598 Patent) issued to Corvita Corporation and listed as the sole inventor, Leonard Pinchuck.

2. On August 18, 2000, a Petition to Correct Inventorship of the '598 Patent was filed which listed three inventors, namely Leonard Pinchuck, Rysler Alcime, and Yasushi Kato. Included in that filing was a Statement Pursuant to 37 C.F.R. § 1.324(b)(1) signed by Rysler Alcime.

3. On September 5, 2000, a Reissue Application was filed for the '598 Patent which was assigned Serial No. 09/657,041. An unexecuted Reissue Application Declaration accompanied that filing, the unexecuted declaration naming all three inventors, namely Leonard Pinchuck, Rysler Alcime, and Yasushi Kato.

4. On September 30, 2003, a Supplemental Reissue Application Declaration was sent to each inventor for signature, including Rysler Alcime. That document was sent via Federal Express® to:

925 N.E. 122nd Street
Miami, Florida 33161

Receipt was confirmed on October 1, 2003 by R. Branchedor. A copy of the relevant confirmation information is attached hereto at Exhibit A.

5. Having not received the executed Supplemental Reissue Application Declaration back from Rysler Alcime, it was again sent, on October 23, 2003, to the same address as the one sent on September 30, 2003, via DHL® courier. Receipt was confirmed on October 24, 2003, by a Z. Alcime. A copy of the relevant confirmation information is attached hereto at Exhibit B.

6. Upon still not having received the executed Supplemental Reissue Application Declaration, a telephone number was found for Rysler Alcime at the above address and a phone call was made to him (at (305) 895-8747) on each of 5 different occasions by the below-named signatory between October 26 and November 14, 2003. No answering machine picked up on any of those occasions and no one answered the phone on any occasion (except for the one instance detailed in paragraph 7). In each case the phone rang for over 15 rings.

7. On one of those occasions, a person answered the telephone and when asked, claimed not to be Rysler Alcime. The person was rather incoherent, and when the below-named signatory asked if the person would take a message and ask Mr. Alcime to call back when he returned, the person responded, "No, you call back later" and hung up.

8. On November 17, 2003, the below-named signatory called the same number and did get an answering machine. A message was left requesting a return call but to date no return call has been received.

9. During the week of November 10, 2003, the below-named signatory called a co-inventor on the Reissue Application, namely Leonard Pinchuk, and inquired about the whereabouts of Mr. Alcime. Dr. Pinchuk responded that the did not know Mr. Alcime's whereabouts, but that he had heard that Mr. Alcime had started an import/export business trading with Haiti and that he did spend several weeks at a time in Haiti.

10. In early December, 2003, the below-named signatory received a call from someone claiming to be Rysler Alcime's wife. The caller indicated that Rysler Alcime was traveling overseas but that he was going to return in late December and would then look at the documents.

11. On or about January 20, 2004, when no word had yet been received from Rysler Alcime, phone calls were again placed to (305) 895-8747 on several occasions, totaling at least 6 times, through January 29, 2004. No contact or answering machine pick-up was achieved.

12. Again on December 8, 2004, we sent to Rysler Alcime a copy of the entire application to the last known address of Mr. Alcime by FedEx Courier. A copy of the documents which were sent are attached.

13. On December 9, 2004, we received an email confirmation stating that our shipment has been delivered (copy enclosed). Also enclosed are detailed results from the FedEx website tracking service stating that this package was delivered.

14. The name and last known address of the non-signing inventor is:

Rysler Alcime
925 N.E. 122nd Street
Miami, Florida 33161

15. For all of the above reasons, the applicants of this Reissue Application believe that a *bona fide* effort has been made to ascertain the whereabouts of Mr. Alcime

and obtain his signature on the declaration, and that he either is refusing to join or has not been found after diligent effort. Accordingly, the applicants respectfully request that the Supplemental Reissue Application Declaration enclosed be accepted as executed by Leonard Pinchuk and Yasushi Kato.

16. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Jonathan H. Spadt

RatnerPrestia

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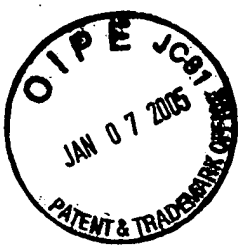
JONATHAN H. SPADT
DIRECT DIAL: 610-993-4248
EMAIL: jhspadt@ratnerprestia.com



December 8, 2004

Via FedEx Courier

Mr. Rysler Alcime
925 N.E. 122th Street
Maimi, Florida 33161

Re: U.S. Patent Application by Leonard Pinchuk et al. for
Expandable Supportive Branched Endoluminal Grafts
Serial No.: 09/657,041
Filed: 09/05/2000
Our Ref.: BSI-430US8
Your Ref.: 93-P0241CIP3-RE

Dear Rysler:

We are enclosing the following for your review and signature:

1) The Reissue Application filing including all of its enclosures dated September 5, 2000;

2) An Information Disclosure Statement filed February 23, 2001;

3) Status Request filed March 5, 2002;

4) A Supplemental Information Disclosure Statement filed May 28, 2002;

5) Amendment filed October 1, 2003 which includes Figures 14-17; Copy of Terminal Disclaimer; Copy of Assignment; PTO-1449; Copy of Certificate of Correction; Copy of patent columns with insertion of corrected text; Supplemental Reissue Oath/Declaration;

6) Communication dated December 9, 2003 which includes Replacement Sheet of Figures 14-17, Partially executed Supplemental Reissue Oath/Declaration, Claims 40-42 (underlined), Original U.S. Patent No. 5,855,598;

7) Information Disclosure Statement filed February 9, 2004;

8) Supplemental Amendment filed June 8, 2004;

9) Information Disclosure Statement filed July 14, 2004;

10) Information Disclosure Statement filed August 6, 2004;

11) Supplemental Information Disclosure Statement filed October 25, 2004; and

12) Supplemental Reissue Application Declaration.

Please sign and date the Supplemental Reissue Application Declaration (number 12 listed above) and return it to us for filing with the U.S. Patent and Trademark Office. For your convenience we are enclosing a return FexEx envelope. Please return this document to us no later than **December 15, 2004**.

Should you have any questions or comments, please let me know.

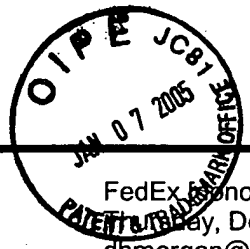
Sincerely yours,

RatnerPrestia

Jonathan H. Spadt

JHS/dhm

Enclosure: As listed above



Denise Morgan

From: FedEx [donotreply@fedex.com]
Sent: Thursday, December 09, 2004 9:26 AM
To: dhmorgan@ratnerprestia.com
Subject: FedEx shipment 792154089306

Our records indicate that the shipment sent from Denise Morgan/RATNER & PRESTIA
to Rysler Alcime has been delivered.
The package was delivered on 12/09/2004 at 9:19 AM and signed for
or released by T.MBA.41475.

The ship date of the shipment was 12/08/2004.

The tracking number of this shipment was 792154089306.

FedEx appreciates your business. For more information about FedEx services,
please visit our web site at http://www.fedex.com

To track the status of this shipment online please use the following:
http://www.fedex.com/cgi-bin/tracking?tracknumbers=792154089306
&action=track&language=english&cntry_code=us

Disclaimer

FedEx has not validated the authenticity of any email address.

Track Shipments
Detailed Results

Quick Help

Tracking number	792154089306	**Reference**	BSI-430US8
Signed for by	Signature release on file	**Delivery location**	Miami, FL
Ship date	Dec 8, 2004	**Delivered to**	Residence
Delivery date	Dec 9, 2004 9:19 AM	**Service type**	Priority Pak
		Weight	1.0 lbs.

Status Delivered

Date/Time		Activity	Location	Details
Dec 9, 2004	9:19 AM	**Delivered**	Miami, FL	Left at front door. No signature required - release waiver on file
	8:28 AM	Departed FedEx location	NEWARK, NJ	
	8:19 AM	On FedEx vehicle for delivery	NORTH MIAMI BEACH, FL	
	7:31 AM	At local FedEx facility	NORTH MIAMI BEACH, FL	
	6:22 AM	At dest sort facility	FORT LAUDERDALE, FL	
	3:43 AM	Departed FedEx location	NEWARK, NJ	
Dec 8, 2004	11:50 PM	Arrived at FedEx location	NEWARK, NJ	
	8:07 PM	Left origin	KING OF PRUSSIA, PA	
	4:38 PM	Picked up	KING OF PRUSSIA, PA	
	9:22 AM	Package data transmitted to FedEx; package not in FedEx possession		

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From

To

Add a message to this email.

Send email

BSI-430US8 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Leonard Pinchuk : Art Unit: 3738

Patent No.: 5,855,598 : Examiner: M. Milano

Issued: January 5, 1999

For: EXPANDABLE SUPPORTIVE BRANCHED ENDOLUMINAL GRAFTS

PETITION FOR CORRECTION OF INVENTORSHIP OF PATENT
(37 C.F.R. § 1.324) AND BROADEN REISSUE PATENT APPLICATION

Assistant Commissioner for Patents
Washington, D.C. 20231

SIR:

Enclosed please find the following:

1. Petition for Correction of Inventorship of Patent (37 C.F.R. § 1.324);
2. Statement Pursuant to 37 C.F.R. § 1.324(b)(1) executed by Rysler Alcime;
3. Statement Pursuant to 37 C.F.R. § 1.324(b)(1) executed by Yasushi Kato;
4. Statement Pursuant to 37 C.F.R. § 1.324(b)(2);
5. Statement of Consent of Assignee to Change of Inventorship Pursuant to 37 C.F.R. § 1.324(b)(3);
6. Recordation Form Cover Sheet;
7. Assignment;
8. Broaden Reissue Patent Application Transmittal form and enclosures listed thereon;
9. Reissue Application Fee Transmittal form;
10. Copy of the Patent along with a copy of the drawings;
11. Declaration and Power of Attorney;
12. Offer to Surrender in Support of Reissue; and
13. Consent of Assignee to Reissue.

Respectfully Submitted,

Jonathan H. Spadt, Reg. No. 45,122

JHS/nr

Dated: September 5, 2000

Suite 301, One Westlakes,
Berwyn, P.O. Box 980
Valley Forge, PA 19482-0980
(610) 407-0700

The Assistant Commissioner for Patents is hereby authorized to charge payment to Deposit Account No. 18-0350 of any fees associated with this communication.

EXPRESS MAIL Label NumberEL512197269US:
I hereby certify that this paper is being deposited, under 37 C.F.R. § 1.10 and with sufficient postage, using the "Express Mail Post Office to Addressee" service of the United States Postal Service on the date indicated above and that the deposit is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231 on: September 5, 2000

Kathleen Libby

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Leonard Pinchuk : Art Unit: 3738

Patent No.: 5,855,598 : Examiner: M. Milano

Issued: January 5, 1999

For: EXPANDABLE SUPPORTIVE BRANCHED ENDOLUMINAL GRAFTS

PETITION FOR CORRECTION OF INVENTORSHIP OF PATENT (37 C.F.R. § 1.324)

Assistant Commissioner for Patents
Washington, D.C. 20231

S I R :

This is a petition for correction of error in nonjoinder of inventors in the above issued patent. It is respectfully requested that the PTO issue a certificate correcting the error. Specifically, it is requested that the inventorship of U.S. Patent No. 5,855,598 be changed from Leonard Pinchuk to Leonard Pinchuk, Rylser Alcime and Yasushi Kato as joint inventors.

As required by 37 C.F.R. § 1.324(b), enclosed with this petition are:

(1) a statement from each person being added as an inventor, namely Rysler Alcime and Yasushi Kato, each of which indicates that the error in inventorship occurred without deceptive intention on their part;

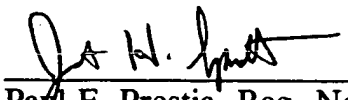
(2) a statement by the original named inventor, namely Leonard Pinchuk, agreeing to the correction of inventorship;

(3) a check in the amount of $130.00 for the petition fee set forth in 37 C.F.R. § 1.17(i); and

(4) the written consent of the Assignee, Corvita Corporation.

Applicants request that the inventorship of the above-identified application be changed from Leonard Pinchuk to Leonard Pinchuk, Rysler Alcime and Yasushi Kato as joint inventors.

Respectfully Submitted,



Paul F. Prestia, Reg. No. 23,031
Jonathan H. Spadt, Reg. No. 45,122
Attorneys for Applicants

JHS/nr

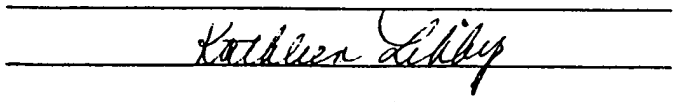
Enclosures: Statements of each added inventor (2);
Statement of original inventor (1);
$130 Check;
Consent of Assignee

Dated: September 5, 2000

Suite 301
One Westlakes, Berwyn
P.O. Box 980
Valley Forge, PA 19482-0980
(610) 407-0700

The Assistant Commissioner for Patents is hereby authorized to charge payment to Deposit Account No. **18-0350** of any fees associated with this communication.

EXPRESS MAIL Label NumberEL512197269US:
I hereby certify that this paper is being deposited, under 37 C.F.R. § 1.10 and with sufficient postage, using the "Express Mail Post Office to Addressee" service of the United States Postal Service on the date indicated above and that the deposit is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231 on: September 5, 2000.



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Leonard Pinchuk	: Art Unit: 3738
Patent No.: 5,855,598	: Examiner: M. Milano
Issued: January 5, 1999	:
For: EXPANDABLE SUPPORTIVE BRANCHED ENDOLUMINAL GRAFTS	:

STATEMENT PURSUANT TO 37 C.F.R. § 1.324(b)(1)

Assistant Commissioner for Patents
Washington, D.C. 20231

S I R :

I, Rysler Alcime, one of the added inventors in the above identified issued patent, hereby declare that the error in inventorship stated in U.S. Patent No. 5,855,598 occurred without any deceptive intent on my part. I understand that a Petition to Correct Inventorship is filed herewith.

I hereby declare that all statements made herein are of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above-identified application or any patent issued thereon.

Respectfully submitted,

Rysler Alcime

8/18/2000
Dated

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Leonard Pinchuk	: Art Unit: 3738
Patent No.: 5,855,598	: Examiner: M. Milano
Issued: January 5, 1999	:
For: EXPANDABLE SUPPORTIVE BRANCHED ENDOLUMINAL GRAFTS	:

STATEMENT PURSUANT TO 37 C.F.R. § 1.324(b)(1)

Assistant Commissioner for Patents
Washington, D.C. 20231

S I R :

I, Yasushi Kato, one of the added inventors in the above identified issued patent, hereby declare that the error in inventorship stated in U.S. Patent No. 5,855,598 occurred without any deceptive intent on my part. I understand that a Petition to Correct Inventorship is filed herewith.

I hereby declare that all statements made herein are of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above-identified application or any patent issued thereon.

Respectfully submitted,

Yasushi Kato

Aug 18, 2000
Dated

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Leonard Pinchuk	: Art Unit: 3738
Patent No.: 5,855,598	: Examiner: M. Milano
Issued: January 5, 1999	:
For: EXPANDABLE SUPPORTIVE BRANCHED ENDOLUMINAL GRAFTS	:

STATEMENT PURSUANT TO 37 C.F.R. § 1.324(b)(2)

Assistant Commissioner for Patents
Washington, D.C. 20231

S I R :

I, Leonard Pinchuk, the original named inventor in the above issued patent, hereby declare that I agree to the correction of inventorship of U.S. Patent No. 5,855,598 to add Rylser Alcime and Yasushi Kato as co-inventors, as requested in the Petition filed herewith.

I hereby declare that all statements made herein are of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above-identified application or any patent issued thereon.

Respectfully submitted,

Leonard Pinchuk 8/15/00

Leonard Pinchuk Dated

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Leonard Pinchuk	: Art Unit: 3738
Patent No.: 5,855,598	: Examiner: M. Milano
Issued: January 5, 1999	:
For: EXPANDABLE SUPPORTIVE BRANCHED ENDOLUMINAL GRAFTS	:

STATEMENT OF CONSENT OF ASSIGNEE TO CHANGE OF INVENTORSHIP PURSUANT TO 37 C.F.R. § 1.324(b)(3)

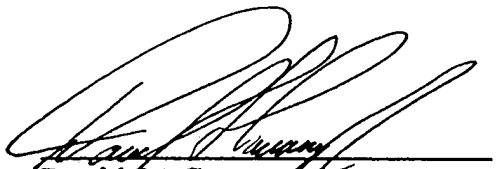
Assistant Commissioner for Patents
Washington, D.C. 20231

S I R :

I, David L. Cavanaugh, represent that I am a Patent Attorney with Boston Scientific Corporation, of One Boston Scientific Place, Natick, MA 10760-1537; that I am authorized to act on behalf of Boston Scientific Corporation; that I have authority to act on behalf of Corvita Corporation with regard to any matters before the U.S. Patent and Trademark Office by virtue of Boston Scientific's ownership of Corvita Corporation and the attached "Authorization to Act on Behalf of Assignee"; that Corvita Corporation is the owner by assignment of all right, title, and interest in and to U.S. Patent No. 5,855,598 via previously recorded assignment to Corvita Corporation (copy enclosed) recorded at the PTO on October 20, 1997 at Reel 8762, Frame 0184; and that neither the subject patent nor the subject invention have been assigned to any other entity. Thus, the extent of Corvita Corporation's interest is in the whole of the subject invention.

Pursuant to 37 C.F.R. § 1.324(b)(3) and as a duly authorized representative of Corvita Corporation, I hereby give the consent of Boston Scientific Corporation, as assignee of the above-identified application, to the change of inventorship in the above-identified application from Leonard Pinchuk to Leonard Pinchuk, Rysler Alcime and Yasushi Kato as joint inventors.

Respectfully submitted,



8/10/00

David L. Cavanaugh
Patent Attorney
Boston Scientific Corporation

Dated

JHS/lsd

LIMITED AUTHORIZATION TO ACT ON BEHALF OF ASSIGNEE REGARDING CERTAIN PATENT MATTERS
EFFECTIVE THROUGH: December 31, 2000

****

I, Paul W. Sandman, as Senior Vice President, Secretary, and General Counsel of Boston Scientific Corporation, the controlling corporation of:

AMS Medinvent S.A.; Boston Scientific BV; Boston Scientific Corporation Northwest Technology Center, Inc.; Boston Scientific Ireland Limited; Boston Scientific Japan KK; Boston Scientific Limited; Boston Scientific Scimed, Inc.; Boston Scientific Technology, Inc.; BSC Technology, Inc.; CardioGene Therapeutics, Inc.; Cardiovascular Imaging Systems, Inc.; Cardiovascular Innovations Canada, Inc.; Corvita Canada, Inc.; Corvita Corporation; Corvita Europe S.A.; E.P. Technologies, Inc.; Laboratoires Corvita S.A.R.L.; Meadox Medicals, Inc.; Meadox Technology, Inc.; NAMIC Eireann Limited; NAMIC International, Inc.; Nilo Holding, S.A.; Schneider (Europe) GmbH; Schneider (USA), Inc.; Schneider Belgium NV; Schneider Holland BV; Schneider Ireland BV; Schneider Puerto Rico; Schneider/NAMIC; Scimed Life Systems, Inc.; Scimed Technology, Inc.; Symbiosis Corporation; and Target Therapeutics, Inc.;

hereby authorize the following registered patent attorneys/agents (1) to act on behalf of any of the corporations identified above, including Boston Scientific Corporation, with regard to any matters before the United States Patent and Trademark Office, any foreign patent offices, and any international patent entities, (2) to execute power of attorney documents on behalf of any of the corporations identified above, including Boston Scientific Corporation, to appoint and/or establish any attorneys, agents, and/or law firms to act on behalf of any of the corporations identified above, including Boston Scientific Corporation, in any foreign or international patent applications filed with any foreign and/or international patent offices, and (3) to execute assignment and ownership documents on behalf of any of the corporations identified above, including Boston Scientific Corporation, with regard to any matters before the United States Patent and Trademark Office, any foreign patent offices, and any international patent offices:

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William J. Shaw	Reg. No. 43,111

Paul W. Sandman
Senior Vice President, Secretary, and General Counsel

January 5, 2000
Date

COMMONWEALTH OF MASSACHUSETTS)
) ss.
COUNTY OF MIDDLESEX)

On this 5th day of January, 2000 before me personally appeared Paul W. Sandman to me known and known to me to be the person described in and who executed the foregoing instrument, and he duly acknowledged to me that he executed the same for the uses and purposes set forth herein.

Notary Public

NONA E. HURD
NOTARY PUBLIC
My Commission Expires Oct. 4, 2002

:680b

PATENT ONLY

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1. Name of conveying party(ies):
Leonard Pinchuk; Rysler Alcime; Yasushi Kato

Additional name(s) of conveying party(ies) attached? ☐ YES ☐ NO

3. Nature of Conveyance:
- ☒ Assignment
- ☐ Merger
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- ☐ Change of Name
- ☐ Correction of Assignment Recordation (previously recorded at Reel ___, Frame ___).
- ☐ Other

Execution Date: August 18, 2000

2. Name and address of receiving party(ies):
Name: Corvita Corporation
Internal Address: 8210 N.W. 27th Street
Street Address: ___
City: Miami State: FL ZIP: 33122
Additional name(s) & address(es) attached? ☐ YES ☐ NO

4. Application number(s) or patent number(s):
If this document is being filed together with a new application, the execution date of the application is: ___
A. Patent Application Number(s) ___ B. Patent Number(s) ___

Additional number(s) attached? ☐ YES ☐ NO

5. Name and address of party to whom correspondence concerning document should be mailed:
Name: Jonathan H. Spadt

Internal Address: Ratner & Prestia

Street Address: Suite 301, One Westlakes, Berwyn, P.O. Box 980

City: Valley Forge State: PA ZIP: 19482-0980

6. Total number of applications and patents involved:

7. Total fee (37 CFR 3.41): $ 40.00
- ☒ Enclosed
- ☐ Authorized to be charged to deposit account

8. Deposit account number: **18-0350**
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To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy of the original document.

Jonathan H. Spadt
Name of Person Signing

J. H. Spadt
Signature

SEPT. 5, 2000
Date

45,122
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USPTO Form 1595 [R&P]

BSI-430US8

ASSIGNMENT

WHEREAS, I, Rylser Alcime of 925 N.W. 122th Street, Miami, Florida 33161and Yasushi Kato of 311 South West, 187th Avenue, Pembroke Pines, FL 33029, (hereinafter referred to as "**ASSIGNOR**") have made an invention entitled EXPANDABLE SUPPORTIVE BRANCHED ENDOLUMINAL GRAFTS, Application Number 863,964, filed May 27, 1997, which matured into U.S. Patent No. 5,855,598;

WHEREAS, the **ASSIGNEE**, Corvita Corporation, 8210 N.W. ~~28th~~ 27th Street, Miami, FL 33122 a corporation organized and existing under and by virtue of the laws of the State of Florida is desirous of acquiring the entire interest in and to said invention and the Letters Patent issued therefor;

LP 8/18/00
YMM 8/18/00
RA 8/18/00

NOW, THEREFORE, in consideration of One Dollar ($1.00) and of other good and valuable consideration, the receipt of which is hereby acknowledged, the undersigned, intending to be legally bound, does hereby sell, assign and transfer to the **ASSIGNEE** the **ASSIGNOR'S** entire right, title and interest, for the United States of America, its territories and possessions, and for all foreign countries, in said invention, including said letters patent all divisions and continuations thereof, all rights to claim priority based thereon, all rights to file foreign applications on said invention, and all reissues thereof, issuing for said invention in the United States of America and in any and all foreign countries.

It is agreed that **ASSIGNOR** shall be legally bound, upon request and at the expense of the **ASSIGNEE** or its successors or assigns or a legal representative thereof, to supply all information and evidence of which the undersigned has knowledge or possession, relating to the making and practice of said invention, to testify in any legal proceeding relating thereto, to execute all instruments and do such other acts as may be necessary and proper to patent the invention in the United States of America and foreign countries in the name of the **ASSIGNEE** and to execute all instruments proper to carry out the intent of this instrument.

ASSIGNOR hereby warrants that no assignment, sale, agreement or encumbrance has been or will be made or entered into which would conflict with this Assignment.

IN WITNESS WHEREOF, this Assignment is executed on the day indicated below.

ASSIGNOR: Typed Name: Rylser Alcime

Signature

Date: 8/18/2000

Witness as to ASSIGNOR: (Optional)

ASSIGNOR: Typed Name: Yasushi Kato

Signature

Date: Aug. 18, 2000

Witness as to ASSIGNOR: (Optional)

Please type a plus sign (+) inside this box → [+]

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Attorney Docket No.	BSI-430US8
First Named Inventor	Leonard Pinchuk et al.
Original Patent Number	5,855,598
Original Patent Issue Date (Month/Day/Year)	January 5, 1999
Express Mail Label No.	EL512197269US

APPLICATION FOR REISSUE OF: *(check applicable box)* [X] *Utility Patent* [ ] *Design Patent* [ ] *Plant Patent*

APPLICATION ELEMENTS

1. [X] * Fee Transmittal Form *(PTO/SB/56)* *(Submit an original, and a duplicate for fee processing)*
2. [X] Specification and Claims *(amended, if appropriate)*
3. [X] Drawing(s) *(proposed amendments, if appropriate)*
4. [X] Reissue Oath / Declaration (original or copy) *(37 C.F.R. § 1.175)(PTO/SB/51 or 52)*
5. Original U.S. Patent
   - [X] Offer to Surrender Original Patent *(37 C.F.R. § 1.178)* *(PTO/SB/53 or PTO/SB/54)*
   - *or*
   - [ ] Ribboned Original Patent Grant
   - [ ] Affidavit / Declaration of Loss *(PTO/SB/55)*
6. Original U.S. Patent currently assigned?
   - [X] Yes [ ] No

   (If Yes, check applicable box(es))
   - [X] Written Consent of all Assignees *(PTO/SB/53 or 54)*
   - [ ] 37 C.F.R. § 3.73(b) Statement [X] Power of Attorney

ACCOMPANYING APPLICATION PARTS

7. [ ] Foreign Priority Claim *(35 U.S.C. 119)* *(if applicable)*
8. [ ] Information Disclosure Statement (IDS)/PTO-1449 [ ] Copies of IDS Citations
9. [ ] English Translation of Reissue Oath/Declaration *(if applicable)*
10. [ ] * *Small Entity* Statement(s) *(PTO/SB/09-12)* [ ] Statement filed in prior application, Status still proper and desired
11. [ ] Preliminary Amendment
12. [X] Return Receipt Postcard *(MPEP 503)* *(Should be specifically itemized)*
13. [ ] Other: .....

** NOTE FOR ITEMS 1 & 10 IN ORDER TO BE ENTITLED TO PAY SMALL ENTITY FEES, A SMALL ENTITY STATEMENT IS REQUIRED (37 C.F.R. § 1.27), EXCEPT IF ONE FILED IN A PRIOR APPLICATION IS RELIED UPON (37 C.F.R. § 1.28).*

14. CORRESPONDENCE ADDRESS

[ ] *Customer Number or Bar Code Label* *(Insert Customer No. or Attach bar code label here)* or [X] *Correspondence address below*

Name	Jonathan H. Spadt Ratner & Prestia				
Address	P.O. Box 980				
City	Valley Forge	*State*	PA	*Zip Code*	19482
Country		*Telephone*	610-407-070	*Fax*	610-407-0701

NAME (Print/Type)	Jonathan H. Spadt	*Registration No. (Attorney/Agent)*	45,122
Signature	Jon H. Spadt	*Date*	SEPT. 5, 2000

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REISSUE APPLICATION FEE TRANSMITTAL FORM

Docket Number (Optional): BSI-430US8

Claims as Filed - Part 1

Claims in Patent	For	Number Filed in Reissue Application	(3) Number Extra	Small Entity Rate	Small Entity Fee		Other than a Small Entity Rate	Other than a Small Entity Fee
(A) 30	Total Claims (37 CFR 1.16(j))	(B) 45	**** 15 =	x $____ =		or	x $ 18 =	270
(C) 3	Independent Claims (37 CFR 1.16(i))	(D) 6	* 3	x $____ =			x $ 78 =	234
				Basic Fee (37 CFR 1.16(h))	$____			$ 690
				Total Filing Fee	$		OR	$ 1,194

Claims as Amended - Part 2

	(1) Claims Remaining After Amendment		(2) Highest Number Previously Paid For	(3) Extra Claims Present	Small Entity Rate	Small Entity Fee		Other than a Small Entity Rate	Other than a Small Entity Fee
Total Claims (37 CFR 1.16(j))	***	MINUS	**	* =	x $____ =		or	x $____ =	
Independent Claims (37 CFR 1.16(i))	***	MINUS	*****	=	x $____ =			x $____ =	
				Total Additional Fee	$			OR	$

* If the entry in (D) is less than the entry in (C), Write "0" in column 3.
** If the "Highest Number of Total Claims Previously Paid For" is less than 20, Write "20" in this space.
*** After any cancelation of claims
**** If "A" is greater than 20, use (B -A); if "A" is 20 or less, use (B - 20).
***** "Highest Number of Independent Claims Previously Paid For" or Number of Independent Claims in Patent (C).

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☒ A check in the amount of $ 1,194.00 to cover the filing / additional fee is enclosed.

Sept. 5, 2000
Date

Signature of Applicant, Attorney or Agent of Record

Jonathan H. Spadt, Reg. No. 45,122
Typed or printed name

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EXPANDABLE SUPPORTIVE BRANCHED ENDOLUMINAL GRAFTS

CROSS REFERENCE TO RELATED APPLICATION

This is a continuation-in-part of application Ser. No. 08/558,028, filed Nov. 13, 1995, now U.S. Pat. No. 5,632,772 and application Ser. No. 08/558,034, filed Nov. 13, 1995, now U.S. Pat. No. 5,639,278, which are each a continuation-in-part of application Ser. No. 140,245, filed Oct. 21, 1993, now abandoned.

BACKGROUND AND DESCRIPTION OF THE INVENTION

This invention generally relates to supportive endoluminal grafts which have the ability to be delivered transluminally and expanded in place to provide a graft that is endoluminally positioned and placed, with the aid of an appropriate inserter or catheter, and that remains so placed in order to both repair a vessel defect and provide lasting support at the location of the graft. In its broadest sense, the graft preferably combines into a single structure both an expandable luminal prosthesis tubular support component and a compliant graft component secured thereto. The expandable supportive endoluminal graft takes on a bifurcated or branched structure made up of components that are designed to be positioned in a bifurcated manner with respect to each other, preferably during deployment or repair and support of vessel locations at or near branching sites. Preferably, the graft component is compliant, stretchable or elastomeric and does not substantially inhibit expansion of the tubular support component while simultaneously exhibiting porosity which facilitates normal cellular growth or invasion thereinto of tissue from the body passageway after implantation.

Elastomeric vascular grafts are known to be made by various methods. Included are methods which incorporate electrostatic spinning technology such as that described by Annis et al. in "An Elastomeric Vascular Prosthesis", *Trans. Am. Soc. Artif. Intern. Organs*, Vol. XXIV, pages 209–214 (1978) and in U.S. Pat. No. 4,323,525. Other approaches include elution of particulate material from tubular sheeting, such as by incorporating salts, sugars, proteins, water-soluble hydrogels, such as polyvinyl pyrrolidone, polyvinyl alcohol, and the like, within polymers and then eluting the particulate materials by immersion in water or other solvent, thereby forming pores within the polymer. Exemplary in this regard is U.S. Pat. No. 4,459,252, incorporated by reference hereinto. Another approach involves the forming of pores in polymers by phase inversion techniques wherein a solventized polymer is immersed in another solvent and the polymer coagulates while the polymer solvent is removed. Also known are spinning techniques such as those described in U.S. Pat. No. 4,475,972. By that approach, a polymer such as a polyurethane in solution is extruded as fibers from a spinnerette onto a rotating mandrel. The spinnerette system reciprocates along a path which is generally parallel to the longitudinal axis of the mandrel and at a controlled pitch angle. The result is a non-woven structure where each fiber layer is bound to the underlying fiber layer.

Also known are stent devices, which are placed or implanted within a blood vessel or other body cavity or vessel for treating occlusions, stenoses, aneurysms, disease, damage or the like within the vessel. These stents are implanted within the vascular system or other system or body vessel to reinforce collapsing, partially occluded,

weakened, diseased, damaged or abnormally dilated sections of the vessel. At times, stents are used to treat disease at or near a branch, bifurcation and/or anastomosis. This runs the risk of compromising the degree of patency of the primary vessel and/or its branches or bifurcation, which may occur as a result of several problems such as displacing diseased tissue, vessel spasm, dissection with or without intimal flaps, thrombosis and embolism.

One common procedure for implanting a stent is to first open the region of the vessel with a balloon catheter and then place the stent in a position that bridges the diseased portion of the vessel. Various constructions and designs of stents are known. U.S. Pat. No. 4,140,126 describes a technique for positioning an elongated cylindrical stent at a region of an aneurysm to avoid catastrophic failure of the blood vessel wall, the stent being a cylinder that expands to an implanted configuration after insertion with the aid of a catheter. Other such devices are illustrated in U.S. Pat. Nos. 4,787,899 and 5,104,399. U.S. Pat. Nos. 4,503,569 and 4,512,338 show spring stents which expand to an implanted configuration with a change in temperature. It is implanted in a coiled configuration and then heated in place to cause the material of the spring to expand. Spring-into-place stents are shown in U.S. Pat. No. 4,580,568. U.S. Pat. No. 4,733,665 shows a number of stent configurations for implantation with the aid of a balloon catheter. U.S. Pat. No. 5,019,090 shows a generally cylindrical stent formed from a wire that is bent into a series of tight turns and then spirally wound about a cylindrical mandrel to form the stent. When radially outwardly directed forces are applied to the stent, such as by the balloon of an angioplasty catheter, the sharp bends open up and the stent diameter enlarges. U.S. Pat. No. 4,994,071 describes a bifurcating stent having a plurality of wire loops that are interconnected by an elongated wire backbone and/or by wire connections and half hitches.

Stents themselves often do not encourage normal cellular invasion and can lead to undisciplined development of cells in the stent mesh, with rapid development of cellular hyperplasia. Grafts alone do not provide adequate support in certain instances. Copending application of Jean-Pierre Dereume, Ser. No. 08/546,524, entitled "Luminal Graft Endoprostheses and Manufacture Thereof" describes grafts that have the ability to carry out dilatation and/or support functions. An expandable tubular support component and an elastomeric graft component are combined into a single device wherein the graft material is secured to either or both of the internal and external surfaces of the expandable support component. The graft material is produced by a spinning technique such as that described in U.S. Pat. No. 4,475,972. Also, luminal endoprostheses with an expandable coating on the surface of external walls of radially expandable tubular supports are proposed in U.S. Pat. Nos. 4,739,762 and 4,776,337. In these two patents, the coating is made from thin elastic polyurethane, Teflon film or a film of an inert biocompatible material. A. Balko et al., "Transfemoral Placement of Intraluminal Polyurethane Prosthesis for Abdominal Aortic Aneurysm", *Journal of Surgical Research*, 40, 305–309, 1986, and U.S. Pat. Nos. 5,019,090 and 5,092,877 mention the possibility to coat stent materials with porous or textured surfaces for cellular ingrowth or with non-thrombogenic agents and/or drugs. The various patents and publications referred to hereinabove are incorporated hereinto by reference.

By the present invention, grafts which are expandable and supportive are provided that expand from a first diameter to a second diameter which is greater than the first. When it is at its first diameter, the expandable supportive graft is of a

size and shape suitable for insertion into the desired body passageway. The material of the graft is substantially inert and preferably has a generally cylindrical cover and/or lining generally over the outside and/or inside surface of the expandable supportive component. Preferably, the cover and/or lining is especially advantageous because it is compliant or elastomeric and porous to encourage desirable growth of tissue thereinto in order to assist in non-rejecting securement into place and avoidance of stenosis development. The porous liner and/or cover material is compliant or elastomeric enough to allow for expansion by up to about 2 to 4 times or more of its unexpanded diameter. Components of the branched or bifurcated expandable supportive endoluminal graft preferably are deployable separately such that each component is properly positioned with respect to the other into the desired branched or bifurcated arrangement. One of the components has a portion which has at least one longitudinally disposed indent to generally define at least two leg portions for receiving one of the other components.

It is a general object of the present invention to provide an improved branched endoluminal graft that is expandable in place and, once expanded, is self-supporting.

Another object of this invention is to provide biocompatible grafts having a plurality of components that are separately expandable in vivo and that are supportive once so expanded.

Another object of the present invention is to provide an improved expandable reinforced graft that is delivered by way of introducers, balloon catheters or similar devices, and which facilitates good tissue ingrowth.

Another object of this invention is to provide an improved endoluminal graft which fully covers diseased or damaged areas for carrying out luminal repairs or treatments, such as repair of aneurysms.

Another object of the present invention is to provide an improved endoluminal graft wherein the endoprosthesis is substantially enclosed within biocompatible compliant material which is presented to the surrounding tissue and blood or other body fluid.

Another object of this invention is to provide an expandable, supportive graft that can be tailored to meet a variety of needs, including a single graft designed to address more than a single objective.

Another object of the present invention is to provide a self-expanding reinforced graft device that is delivered in its elongated and compressed state from within a tubular member and deployed by moving same out of the tubular member, which device is especially suitable for component deployment.

Another object of this invention is to provide a bifurcated trunk component that is deployed in a collapsed state and expanded in vivo to a branched device for use in treatment and/or repair at branched vessel locations.

A further object of the present invention is to provide a component branched endoluminal graft having a longitudinally creased trunk component and at least one cylindrical branch component, which components are expanded separately after endoluminal delivery and which form a bifurcated graft once positioned with respect to each other and expanded.

Another object of this invention is to provide an improved method of forming a branched endoluminal graft incorporating a longitudinal creasing procedure.

Another object of the present invention is to provide an improved method of assembling a branched endoluminal graft.

These and other objects, features and advantages of this invention will be clearly understood through a consideration of the following detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be further elucidated in the following description with reference to the drawings, in which:

FIG. 1 is a perspective view, partially cut away, of an expandable supportive endoluminal graft construction in accordance with the invention;

FIG. 2 is a cross-sectional view along the line 2—2 of FIG. 1;

FIG. 3 is a perspective view, partially cut away, of another embodiment of the expandable supportive endoluminal graft construction;

FIG. 4 is a cross-sectional view along the line 4—4 of FIG. 3;

FIG. 5 is a perspective view, partially cut away, of a further embodiment of the expandable luminal graft construction;

FIG. 6 is a cross-sectional view along the line 6—6 of FIG. 5;

FIG. 7 is a perspective view, partially cut away, of a bifurcated expandable supportive endoluminal graft construction;

FIG. 8 is a cross-sectional view along the line 8—8 of FIG. 7;

FIG. 9 is a somewhat schematic view illustrating an early step in the implantation of a device such as shown in FIG. 7;

FIGS. 10, 11 and 12 are generally schematic views along the lines of FIG. 9 showing expansion of the main body and the branches of this bifurcated device;

FIG. 13 shows this bifurcated supportive graft after completion of the expansion procedure;

FIG. 14 illustrates another embodiment of a bifurcated expandable supportive endoluminal graft construction;

FIGS. 15, 16 and 17 illustrate implantation and assembly of the graft of FIG. 14;

FIGS. 18, 19, 20 and 21 illustrate a component branched graft and various stages of its separate, component deployment within a body vessel to repair an aneurysm, FIGS. 18 and 19 showing deployment of a preferred branched, longitudinally indented trunk component, and FIGS. 20 and 21 showing separate deployment of two branch components within the trunk component;

FIG. 22 is a top plan view of an embodiment of a branching trunk component in accordance with the invention;

FIG. 23 is a cross-sectional view along the line 23—23 of FIG. 22;

FIG. 24 is a side elevational view of the branching trunk component as illustrated in of FIGS. 22 and 23;

FIG. 25 is an end view of the structure as shown in FIG. 24;

FIG. 26 is a perspective, generally exploded view of an example of a fixture suitable for forming the longitudinal crease in this trunk component;

FIG. 27 is a longitudinal broken-away view of the fixture of FIG. 26 with a braided cylindrical tube positioned therein;

FIG. 28 is a view generally in accordance with FIG. 27, showing formation of opposing crease indents in the braided cylindrical tube during formation of this trunk component;

FIG. 29 is a top plan view showing assembly of supportive endoprosthesis leg components into a branching trunk component according to the invention;

FIG. 30 is an end view of the structure as shown in FIG. 29;

FIG. 31 is a perspective view of another embodiment of a branching trunk component in accordance with the invention;

FIG. 32 is a cross-sectional view along the line 32—32 of FIG. 31; and

FIG. 33 is a perspective view of a modified embodiment of a branching trunk component, having a section of enhanced hoop strength.

DESCRIPTION OF THE PARTICULAR EMBODIMENTS

An embodiment of expandable supportive luminal graft construction is generally illustrated in FIG. 1 at 21. This embodiment includes a braided tubular support component having generally helically wound rigid but flexible strand or wire elements, some of which have the same direction of winding but are axially displaced from one another, and others of which cross these windings and are also axially displaced with respect to each other. The actual structure can be generally braided as illustrated in Wallsten U.S. Pat. No. 4,655,771, incorporated by reference hereinto, or as found in self-expanding braided flat wire Wallstent® devices. Both a cover 23 and a liner 24 are illustrated in FIGS. 1 and 2. Either cover 23 or liner 24 can be omitted if there is no desire to substantially encapsulate the tubular support component 22.

With more particular reference to the illustrated cover 23 and liner 24, when included, they may be formed by an electrostatic spinning process in this illustrative embodiment. Details regarding electrostatic spinning techniques in general are found in Bornat U.S. Pat. No. 4,323,525 and in Bornat European patent publication No. 9,941, as well as in the Annis et al. article discussed hereinabove, the disclosures of which are incorporated by reference hereinto. With further reference to the application of this technology to the expandable supportable luminal grafts of the present invention, random pattern filaments are formed and electrostatically directed toward a charged mandrel in order to form a random pattern of electrostatically generally cross-linked filaments which take on the configuration of a mat having a cylindrical shape. The filament diameters are particularly fine, as is the pore size of the mat so constructed. A typical range of filament diameters is between about 0.5 micron and about 5 microns, and a typical pore size of the electrostatically spun fiber is between about 3 microns and about 20 microns.

Liner 24 is formed directly on the rotating mandrel by this electrostatic spinning procedure. Thereafter, one of the tubular support components discussed herein, such as the generally braided tubular support 22, is placed over the liner 24 still on the mandrel. In the case of the tubular support 22 in a form that is not spring loaded, this includes longitudinally extending the tubular support 22, such as by pulling one or both of its ends, which thereby decreases its diameter so that it fits snugly over the liner 24. When the generally braided tubular support 22 is of a spring-into-place type, a hold-down member (such as shown in FIGS. 18 and 20) is used to prevent automatic radial expansion prior to deployment. When the expandable supportive graft 21 is to include a cover 23, the mandrel is again rotated, and the electrostatic spinning is again accomplished in order to form the cover 23

directly over the tubular support 22. This will also create some bonding between the thus formed cover 23 and the liner 24 at openings between the strands or wires of the woven tubular support 22 or the like. This bonding can be facilitated by uniformly compressing the outer fibers with a soft silicone roller or sponge such that the still tacky outer fibers bond to the inner fibers thereby encapsulating the tubular support within the graft.

Bonding may also be achieved in this or other embodiments by heat welding and/or by the use of adhesives such as hot melt adhesives, primers, coupling agents, silicone adhesives, and the like, and combinations of these. Examples include aliphatic polycarbonate urethane hot melts and silicone rubber adhesives.

It is important to note that each of the cover 23 and the liner 24, when either or both are present, is made of an elastomeric material which retains its compliant properties after construction of the expandable supportive graft 21 is completed. In this regard, the graft itself is also elastomeric and compliant. Accordingly, the graft 21 is delivered transluminally, such as by being pulled down onto the balloon of a catheter or into an inserter tube and then percutaneously inserted and positioned to the location where the repair is needed. For a non-spring loaded graft, the balloon is then inflated to longitudinally shorten and radially expand the graft 21 into engagement with the vessel walls. Because of the compliance of the cover 23 and/or liner 24, and because of the hoop strength of the braided tubular support 22, the graft 21 will remain in place. In the illustrated embodiment, ends 25 of the tubular support are exposed and are not covered by the cover 23. This allows the exposed end portions 25 to directly engage the vessel wall, if desired in the particular application, in order to assist in anchoring the graft 21 in place. Liner 24 also can be sized so as to not cover the exposed ends 25, or it can extend to or beyond the edge of the ends 25 when it is desired to avoid or minimize contact between the tubular support and the blood or other fluid flowing through the vessel being repaired or treated.

Alternatively, when a braided tubular support such as that illustrated in FIGS. 1 and 2 is incorporated into the graft according to the present invention in a non-spring-loaded form, transluminal delivery can be made by way of a catheter or tool having means for longitudinally compressing the endoprosthesis until it has expanded radially to the desired implanted diameter. Such equipment typically includes a member that engages one end of the endoprosthesis and another member which engages the other end of the endoprosthesis. Manipulation of proximally located controls then effects relative movement of the members toward each other in order to thereby longitudinally compress the endoprosthesis. Delivery tools for spring-loaded grafts include a sleeve that maintains the graft at its compressed diameter until the graft is positioned for deployment such as from the end of an insertion catheter to its auto-expanded state.

With reference to the embodiment illustrated in FIGS. 3 and 4, an expandable supportive graft is illustrated at 31. The illustrated tubular support component 32 is constructed of sinusoidally configured wire helically wound into a tubular shape. General structures of these types are generally discussed in Pinchuk U.S. Pat. No. 5,019,090, incorporated by reference hereinto. A cover 33 can be positioned over the tubular support 32 and/or a liner 34 can be positioned along its lumen. In this illustrated embodiment, the cover 33 and liner 34 are constructed of porous polymers, the pores thereof having been made by elution or extraction of salts

and the like, such as described in MacGregor U.S. Pat. No. 4,459,252, incorporated by reference hereinto. Generally speaking, the porosity is determined by the size of the elutable particles as discussed herein and by the concentration of those particles as a percent by volume of a pre-elution mixture thereof with the polymer of the cover or liner. When a graft 31 having both a cover 33 and a liner 34 is prepared, a mandrel or rod is dipped into a liquid polymer having elutable particles as discussed herein dispersed therewithin. After dipping, the polymer covered rod is contacted with, such as by dipping or spraying, a solvent, for the elutable particles, such as water, thereby forming the eluted porous liner 34. Thereafter, the tubular support 32 is positioned thereover and pressed down into the liner. Then, the rod and the assembly thereon are again dipped into the mixture of polymer and elutable particles, followed by setting and contact with solvent to remove the elutable particles in order to form the eluted porous cover 33. It is also possible to directly extrude the particle-containing polymer into a tubular shape.

Elutable particles which can be used in the making of the eluted porous cover 33 and liner 34 include salts such as sodium chloride crystals, sodium carbonate, calcium fluoride, magnesium sulfate and other water-soluble materials that are readily dissolved by the utilization of water as an elution medium. Other particles that are soluble in organic solvents and the like can be substituted as desired. Further particles include sugars, proteins, and water-soluble hydrogels such as polyvinyl pyrrolidone and polyvinyl alcohol. Suitable polymer materials are as discussed elsewhere herein, the pore size being on the order of about 10 microns to about 80 microns.

As with the other embodiments, when desired, ends 35 of the support component 32 can be exposed either on one or both of its cylindrical faces in accordance with the needs of the particular repair or treatment to be carried out. With this approach, the exposed ends 35 will assist in maintaining the graft 32 in place by mechanical engagement between the exposed ends 35 and the vessel being repaired or treated and/or by tissue ingrowth. The anchoring aspect of the exposed ends of the tubular support can be enhanced by continued radial expansion of the balloon or other deployment means which will permit the exposed ends to expand radially outwardly in an amount somewhat greater than that of the rest of the expandable supportive graft and into the surrounding tissue. It is also contemplated that mechanical means can be used to assist in joining the exposed ends of this embodiment or of other embodiments to the vessel wall. An illustrative example in this regard is the use of translumenally delivered staples which can take on the appearance of rivets. Especially advantageous are staples made of an elastomeric material. Illustrated staples are shown at 36 in FIG. 3. They can be incorporated at other locations as well along the graft. One or more windows 37 can be formed through the cover and/or liner and/or tubular support in order to feed outside branch arteries or other vessels.

FIGS. 5 and 6 illustrate a further embodiment of an expandable supported graft, generally designated as 41. Shown is a mesh tubular support component, generally designated as 42, such as those of the type illustrated in Palmaz U.S. Pat. No. 4,733,665, incorporated by reference hereinto. These are non-woven mesh-type cylinders or slotted tubes wherein most or all of the individual components are either integrally joined together such as by welding or are integrally formed from a single tube. The resulting endoprostheses are malleable enough so as to be expandable by a balloon of a catheter. Usually, these endoprostheses have particularly high hoop strengths.

Cover 43 and/or liner 44 are made of polymers rendered porous by phase inversion techniques. In accordance with these techniques, a polymer such as a polyurethane is dissolved in a solvent therefor, for example a water-soluble polar solvent, such as dimethyl acetamide, tetrahydrofuran and the like, in order to form what is known as a lacquer. A mandrel or rod is dipped into the lacquer. Thereafter, the dipped rod is contacted with an inversion solvent, such as by dipping in water or a mixture of alcohol and water. This inversion solvent must readily dissolve the polymer solvent of the lacquer, while at the same time being a poor solvent for the polymer. Under these conditions, the polymer coagulates and the polymer solvent of the lacquer is removed and replaced with the inversion solvent. The inversion solvent pulls the polymer solvent out of the polymer on the rod and forms particularly fine pores having a pore size on the order of about 0.5 micron to about 20 microns. The thus formed liner 44 having phase inversion pores is then dried.

Next, the tubular support component 42 is secured over the liner 44 and is preferably radially compressed onto and into the liner. Thereafter, the cover 43 having phase inversion pores is formed in accordance with the same phase inversion steps as discussed hereinabove for preparation of the liner 44. If desired, either the liner or the cover can be omitted. Cover 43 and liner 44 are thus formed in accordance with a displacing step wherein precipitating non-solvent molecules are substituted for non-precipitating solvent molecules dispersed throughout the lacquer coating. This procedure develops advantageous elastic characteristics. Further details regarding the phase inversion procedure are found in Lymann et al. U.S. Pat. No. 4,173,689, incorporated by reference hereinto.

FIGS. 7 and 8 illustrate an embodiment wherein the graft takes the form of a bifurcated expandable supportive graft, generally designated at 51. Included is a joined-ring bifurcated tubular support 52. Also shown are a bifurcated cover 53, a bifurcated lining 54 and exposed ends 55, 56, 57. This particular bifurcating graft is well-suited for insertion into a branching vessel.

The tubular support includes a plurality of rings or loops 58 connected by flexible interconnections 59. Constructional details of embodiments of the rings or loops 58 and of the flexible interconnections 59 are found in MacGregor U.S. Pat. No. 4,994,071, incorporated by reference hereinto. The flexible interconnections 59 join the rings or loops 58 into a configuration having a main body or trunk 61 and one or more branches 62. Flexible interconnections 59 extend longitudinally from the axis of each of the main body or trunk 61 and branch 62, 63. At least one such flexible interconnection joins each branch to the trunk. The loops 58 in the main body are substantially parallel to each other, and the loops 58 in each branch 62, 63 are substantially parallel to each other.

The bifurcated cover 53 and bifurcated liner 54 must each, when provided, be especially elastomeric so as to follow the expansion and contraction of the rings or loops 58 that takes place during preparation, transluminal insertion, deployment and the like. Cover 53 and liner 54 will also take on a bifurcated construction. In one embodiment, the liner and/or cover for each of the trunk 61 and branch 62, 63 are made on a cylindrical mandrel, assembled and joined, such as by suitable biocompatible adhesive, fusion, sewing, suturing or other means of joining and/or sealing. Alternatively, a Y-shaped or branched mandrel can be used. The bifurcating liner is then formed thereon by processes such as those discussed herein, including electrostatic spinning, or dipping followed by elution or phase inversion procedures much in

the same manner as described herein when straight cylindrical mandrels or rods are used for constructing the non-bifurcated grafts in accordance with this invention. Fiber winding can also be practiced. Bifurcated cover 53 is made in a similar manner by application of the porous cover material over the bifurcated endoprosthesis.

With reference to the bifurcated endoprosthesis, the bifurcated cover 53 and/or bifurcated liner 54 could be made by fiber winding approaches, such as those described in Wong U.S. Pat. No. 4,475,972, the subject matter thereof being incorporated by reference hereinto. Polymer in solution is extruded into fibers from a spinnerette onto a rotating mandrel. The spinnerette is reciprocated along the longitudinal axis of the mandrel at a controlled pitch angle, resulting in a non-woven cylinder wherein each fiber layer is bound to the underlying layer. Control of the pitch angle allows for control of the compliance and kink resistance of the cover and/or liner. In an especially advantageous arrangement when using these fiber spinning techniques in forming an expandable supportive graft in accordance with the general aspects of this invention which has both a liner and a cover, the cover is physically bonded to the liner by the use of an electrostatic field to enable penetration of the cover overlay of fibers through the interstices of the support components in order to improve the bonding of the cover and/or liner fibers to each other and/or to surfaces of the support component.

With more particular reference to balloon deployment of expandable supportive grafts, this is illustrated with some particularity in connection with bifurcated endoluminal grafts in FIGS. 9, 10, 11, 12 and 13. As shown in FIG. 9, two guidewires 64, 65 are inserted into the bifurcating vessel, each of them into different legs 66, 67 of the bifurcating vessel. Thereafter, the unexpanded bifurcated expandable supportive graft 51 is slipped over the proximal ends of the guidewires and routed to the branches of the blood vessel. The unexpanded bifurcated graft can be introduced from an arteriotomy proximal to the bifurcation such as from the brachial artery in the arm, or the unexpanded bifurcated graft can be introduced from the femoral artery in the leg, pushed proximally past the bifurcation and then pulled back distally into both iliacs to form the trunk and bifurcation.

The two branches 62, 63 of the graft 51 are routed separately over the guidewires 64, 65, respectively, and guided, typically with the help of a guide catheter, into the patient until the graft is positioned as shown in FIG. 9. The graft 51 is initially fixed in place as follows. One of the guidewires 65 is removed, and a balloon catheter 68 is inserted into the main body or trunk 61 and inflated to expand the trunk 61 into contact with the vessel walls. This deployment is suitable to secure the graft 51 in place at that location of the vessel.

The balloon of balloon catheter 68 is then deflated. If this balloon catheter is also suitable for use in expanding the branches 62, 63 of the graft 51, same is then inserted into an unexpanded branch 62 and radially expanded as generally shown in FIG. 11. If the balloon of catheter 68 is not suitable in this regard, then another balloon catheter 69 effects this function. FIG. 12 shows inflation of the other branch 63 of the graft 51 in a similar manner. FIG. 13 illustrates the fully deployed and expanded bifurcated support graft 51 positioned in place within the bifurcated location. Alternatively, a bifurcated dilation balloon on a bifurcated catheter (not shown) can replace the single-balloon catheter(s) 68, 69.

Preferably the branched and assembled expandable supportive graft is of the spring-into-place type; as such, it will

be manipulated to be reduced in diameter and placed within an overlying and bifurcated restraining guiding catheter or the like and will be passed over guidewires and contained within the guiding catheter until proper placement within the bifurcating location. This type of bifurcated expandable supportive graft is deployed by being ejected into place, typically by advancing a small inner catheter through the guiding catheter into contact with the bifurcating graft in accordance with the procedure generally used for spring-into-place stents.

The deployment procedures illustrated in FIGS. 9 through 13 can be characterized as prograde deployment. Retrograde deployment is also possible. The entire bifurcating graft for retrograde deployment is advanced over a single guidewire through one branch of the blood vessel past the point of bifurcation. A second guidewire is then steered down the opposite limb of the graft, and a snare is used. The snare, which is passed retrograde through the opposite vessel, is then used to pull the guidewire into place. Partial balloon inflation in the unbranched or trunk portion of the blood vessel is then used to draw the graft down into position prior to balloon dilatation of both the trunk and branched portions of the graft. Because blood flow is prograde under these circumstances, the contact between the bifurcation of the graft and the bifurcation of the blood vessel helps to prevent the graft from migrating distally, thus reducing the need for active fixation of the graft to the blood vessel.

Another bifurcated endoprosthesis or expandable supportive graft is generally designated 81 in FIG. 14. Separate components are included. In this case tubular supporting component(s) are, prior to deployment, separate from a trunk component. In this embodiment, a fully independent tubular supporting component 82 is located at the trunk position of the graft 81. A bifurcated stretchable wall 83 is in contact with the independent tubular supporting component 82 as either or both of a cover or liner. In addition to being substantially coextensive with the independent tubular supporting component 82 at a trunk portion 84 thereof, the stretchable wall 83 includes at least two generally tubular stretchable branch sleeves 85, 86 which are initially devoid of a supporting component. Separate tubular supporting components 87, 88 (FIGS. 16 and 17) are also included.

Implantation of this bifurcated expandable supportive graft is depicted in FIGS. 14, 15, 16 and 17. Dual guidewires 64, 65 can be used to properly position the unexpanded bifurcated graft 81 within the bifurcating vessel as shown in FIG. 14. A balloon catheter 68 or similarly functioning device is inserted into the main body of the device so as to expand the independent tubular supporting component 82 and the trunk portion 84 of the bifurcated stretchable wall 83. This deployment initially secures the bifurcated supporting graft into place at that location of the vessel, as shown in FIG. 15. The balloon catheter is then deflated and removed or positioned for use in the next step.

A suitable balloon catheter 69 or the like is next used to deploy and expand in place a branch tubular expandable supporting component 89, as illustrated in FIG. 16. A similar step deploys and expands in place another branch tubular expandable supporting component 90, as generally shown in FIG. 17. The bifurcated stretchable wall 83 and the expandable supporting components may be made with the materials and constructions discussed herein and may be subjected to various treatments as discussed.

A further bifurcated endoprosthesis or expandable supportive graft is one in which the separate components are each expandable supportive graft members. These separate

components are illustrated in FIG. 18 through FIG. 21, which also illustrate their separate deployment with respect to each other within an aortic trunk. Same is shown in connection with treating an aneurysm such as an abdominal aorto-iliac aneurysm. The device includes a trunk component 101 which, in the illustrated use, is designed to extend from below the renal arteries to a location between the proximal neck of the aneurysm and the aorto-iliac bifurcation. It will be understood that this trunk component could also be shorter so that it terminates just below the proximal neck of the aneurysm, for example of a length which terminates within the dent or crease 124. In addition, the component bifurcated expandable supportive graft of this embodiment is self-expanding and is deployed by means an introducer containing compressed expandable supportive graft components.

More particularly, and with reference firstly to FIG. 18, a guidewire 102 is first inserted in accordance with known procedures so as to traverse the aneurysm 103. Next, an introducer, generally designed as 104 having the trunk component therewithin in a radially compressed state is inserted over the guidewire 102. The introducer is maneuvered such that it is properly positioned as desired, in this case at a location distal of the distal end of the aneurysm. Then, the sheath 105 of the introducer is withdrawn, such as by sliding it in a proximal direction while the remainder of the introducer 104 remains in place. As the sheath is withdrawn, the trunk 101 expands, eventually achieving the deployed or implanted position shown in FIG. 19. At this stage, the distal portion 106 of the trunk is well anchored into the blood vessel wall and is suitably deployed.

FIG. 20 shows an introducer, generally designated as 107, having an independent tubular expandable supportive graft leg component 108 (FIG. 21) radially compressed therewithin. In this illustrated embodiment, this leg component is an iliac component of the bifurcated supportive graft being assembled within the body vessel. The introducer 107 is advanced until this iliac component is moved into a leg 109 of the already deployed trunk component 101. This positioning is illustrated in FIG. 21. It will be noted that the iliac tubular supportive graft component 108 extends from well within the leg 109 to a location proximal of the aneurysm in the iliac artery 110.

In a previous step, a guidewire had been passed through the appropriate vessel to iliac artery 112 until it crossed the aneurysm 103, while passing through the other leg 113 of the deployed trunk component 101. When the introducer for the previously radially compressed iliac component 115 had been removed, the component 115 had expanded radially and was deployed. Thus, the entirety of the bifurcated endoprosthesis or expandable supportive graft in accordance with this embodiment is fully deployed and assembled together as shown in FIG. 21, as well as generally depicted in FIGS. 29 and 30.

It will be noted that it is not required to actually attach the trunk component 101 and the tubular components 108, 115 together. In other words, these components are generally telescopically positioned with respect to each other. This telescopic feature allows some slippage between the trunk component and the tubular leg components, thereby providing a telescopic joint which functions as a slip bearing. It will be appreciated that it is generally desirable to firmly anchor portions of the bifurcated endoprosthesis within healthy vessel wall tissue. This can be achieved by the hoop strength of the supportive graft or by taking measures to enhance hoop strength at its ends, or by providing grasping structures such as hooks, barbs, flared ends and the like.

During pulsetile blood flow and possibly during exercise by the person within which the endoprosthesis is implanted, tension and elongation forces are imparted to the endoprosthesis. In structures that do not have a telescopic joint or some other means to relieve the stress developed by this tension, a considerable amount of stress can be placed on the anchoring sites and/or the attachment components, potentially allowing for dislodgement at the anchoring sites or breakage of attachment components.

FIGS. 22, 23, 24 and 25 further illustrate a trunk component 101. It includes a common trunk portion 118 and a branched portion, generally designated as 119. The branched portion includes the legs 109 and 113. In this embodiment, a further common trunk portion 120 is located opposite the other common trunk portion 118 and extending from the branched portion 119. Thus, the overall configuration of the trunk component is that of a double-lumen length located between two single-lumen lengths. The common trunk portion 118 can be positioned, for example, in the aortic artery, the branched portion 119 provides a bifurcation structure to direct blood flow into the two iliac arteries, and the further common trunk portion 120 facilitates deployment of the leg components into the branched portion 119, acting in the nature of a funnel for each guidewire, introducer and contracted leg component.

Trunk component 101 includes a stent or tubular supporting component 121. Also included is a liner, generally designated as 122. A further liner 123 preferably is located interiorly of the liner 122. Liners 122, 123 are secured within the stent component 121 in order to provide proper porosity for an endoprosthesis.

Trunk component 101 includes one or more indents, such as indent 124 and indent 125. A third, a fourth, or further indents can be provided depending upon the degree of branching desired. It will be appreciated that one or more tubular expandable supportive leg graft components will be provided in order to slide into the branched passageways which are thus defined by the indent(s). In the illustrated embodiment, one such leg component 108 slidingly engages an opening 126 of the trunk component leg 109, while a second leg component 115 slidingly and expansively fits within opening 127 of the leg component 115.

With particular reference to FIGS. 31–33, this shows a trunk component 101c which has a function and a configuration along the lines of trunk component 101, except only the liner defines the indent or indents. In this arrangement, the tubular supporting component is cylindrical in cross-section substantially throughout its length.

FIG. 31 illustrates the trunk component 101c. It includes a common trunk portion 118c and a branched portion, generally designated as 119c. The bifurcated or branched portion includes the legs 109c and 113c. In this embodiment, a further common trunk portion 120c is located opposite the other common trunk portion 118c and extends from the branched or bifurcated portion 119c. Thus, as with trunk component 101, the overall configuration of trunk component 101c is that of a double-lumen length located between two single-lumen lengths.

Trunk component 101c includes a stent or tubular supporting component 121c, as perhaps best seen in FIG. 32. Also included is a liner, generally designated as 122c. This liner 122c has a body portion 123c and the legs 109c and 113c which open into another body portion 151.

Each leg 109c, 113c is secured to the generally tubular stent component 121c at outside portions thereof, particularly at adhesion zones 124c and 125c. The remainder of the

leg portions 109c and 113c are not so bonded to the stent portion 121c. This facilitates formation of the leg portions, which are typically pinched along the length of the legs in order to form at least one internal seam 126c. Leg openings 127c and 128c are thereby generally defined between this seam 126c and the adhesion zones 124c and 125c.

In FIG. 33, means are included in the trunk component 101d which provides enhanced securement upon implantation. A stent component 129d is included which has a substantially higher pitch angle (for example, between about 140° and 180°) than does the stent portion 121d therebelow within which the legs are positioned (for example, at a pitch angle of between about 70° and 90°). This higher pitch angle zone imparts a greater hoop strength upon deployment than does the stent 121c of the trunk component 101c. A barb 130 is also shown in order to further assist in securement of the endoprosthesis to the artery wall. When desired, the barb-type of structure can be a hacking ring and barb formed out of the stent strand during its formation into the cylindrical supportive member.

Any of the various expandable supportive endoluminal graft, or stent graft, constructions discussed or referred to herein can be used in order to construct devices in accordance with this embodiment. Other modifications may also be incorporated, including tubes having stepped diameters or conical ends. The stent component can be made with flat wires or with pairs of wires or multifilament wires. They can incorporate balloon expandable stents, self-expanding stents, and combinations of balloon expandable stents and self-expanding stents. Use can be made of ancillary equipment such as endoluminal stapling devices or suturing devices in order to facilitate securement at the aneurysm neck, for example. Also, a portion of the stent component without a liner component or the like thereon can project at the proximal end of the endoluminal component, such as at a location which would be above the renal arteries. The objective is also to help to secure the device in place.

The prosthesis as discussed is deployed to replace or repair tubular bodies such as blood vessels, tracheas, ureters and the like, accommodating more than one conduit in order to divert flow to other branches of the tubular body. This allows for repair of a bifurcated area which is difficult to repair using a single-lumen device or a plurality of individual single-lumen devices. It is suitable for repair of damages branched conduits or, conversely, to repair conduits which converge into a single branch.

A preferred use for the bifurcating endoluminal grafts discussed herein is for insertion into a branching blood vessel. Same is typically suitable for use in the coronary vasculature (the right, left common, left anterior descending, and circumflex coronary arteries and their branches) and the peripheral vasculature (branches of the carotid, aorta, femoral, popliteal arteries and the like). These bifurcated devices are also suitable for implantation into other branching vessels such as in the gastrointestinal system, the tracheobronchial tree, the biliary system, and the genitourinary system.

It will be appreciated that the expandable supportive grafts in accordance with the present invention will dilate and/or support blood vessel lesions and other defects or diseased areas, including at or in proximity to sites of vascular bifurcations, branches and/or anastomoses. The expandable supportive graft is an integral structure that incorporates the expandable support component into the wall or walls of the elastomeric graft. Covers and/or linings that make up the grafts interface with body components that

facilitate normal cellular invasion without stenosis or recurrent stenosis when the graft is in its expanded, supportive orientation. The graft material is inert and biocompatible. The expandable supportive graft can be expanded from a smaller diameter insertion configuration to a larger diameter implantation configuration by the application of radially outwardly directed forces provided by expanding the endoprosthesis with a balloon catheter, using an ejection tube that allows a spring-into-place structure to be deployed from the end of a catheter into its expanded configuration, or by using a support component made of certain alloys exhibiting thermotransition characteristics by which they expand when heated, for example.

In addition to the support component structures illustrated herein, support structures include others having spring characteristics and those having a coil with circumferentially oriented fingers such as shown in Gianturco U.S. Pat. No. 4,800,882, incorporated by reference hereinto. U.S. Pat. Nos. 5,061,275, 5,219,355 and 5,336,500 relate to expanding or self-expanding endoluminal devices. Typically, these devices center on the use of a metallic structure imparting expansion attributes. U.S. Pat. Nos. 4,994,071 and 5,360,443 describe bifurcated devices which use expandable metallic stent structures and textile materials allowing branching of fluid flow. In general, materials of these patents, incorporated by reference hereinto, can be utilized in constructing components of the present invention.

More specifically, the tubular supportive component preferably is a braided tubular stent body made of metal alloy or any other material that is flexible, while being rigid and resilient when thus braided. Spring-type metals are typically preferred, such as stainless steel, titanium, stainless steel alloys, cobalt-chromium alloys, including alloys such as Elgiloy, Phynox and Conichrome. Thermal transition or memory function alloys such as nickel-titanium alloys including Nitinol are also suitable. Malleable metals including tantalum would be especially suitable for a structure that is not self-expanding.

Concerning the materials for the liner(s), they are typically polymeric materials in the form of a membrane or textile-like material, the objective being to reduce the porosity of the stent for proper tissue ingrowth and fluid tightness. Exemplary polymeric materials include polyesters such as polyethylene terephthalate, polyolefins such as polypropylene, or elastomeric materials such as polyurethane or silicone rubber. Combinations of these materials are also possible. In an especially preferred arrangement, the exterior liner which engages the tubular supportive component **121**, when provided, is made of a double tricot polyester mesh knit, typically a Dacron type of material, while the interior liner, **122***c* is made of a polyurethane. In an especially preferred arrangement, a thin coating or cover of polymer is provided over the braided wires of the tubular supportive component.

With further reference to the material out of which the cover and/or liner of the grafts in accordance with the present invention are made, the material must be stretchable with respect to the support component so that it will follow the movement of the endoprosthesis between its fully collapsed and expanded or implanted configurations. Polyurethanes are preferred. Particularly preferred is an especially crack-resistant, elastomeric and pliable polycarbonate urethane as described in Pinchuk U.S. Pat. Nos. 5,133,742 and 5,229,431, incorporated by reference hereinto.

In addition, various surface treatments can be applied to render the surfaces of the expandable supported graft more

biocompatible. Included are the use of pyrolytic carbon, hydrogels and the like. The surface treatments can also provide for the elution or immobilization of drugs such as heparin, antiplatelet agents, antiplatelet-derived growth factors, antibiotics, steroids, and the like. Additionally, the coating and/or liner can be loaded with drugs such as those discussed herein, as well as lytic agents in order to provide local drug therapy.

It will be noted that the indent(s) such as indents 124, 125 and the seams(s) such as internal seam 126*c* are longitudinally disposed and generally define at least two leg portions, each with a diameter less than the diameter of the main body. Each indent has an internal longitudinal surface such as longitudinal edge 128, 129. These edges can be in contact with one another. If desired, they can be secured together such as with sutures, adhesives, wires, clips or the like (not shown). One or two such indents or creases produce an asymmetrical or a symmetrical bifurcation as desired. In another exemplary approach, three indents would form a trifurcated device. Additional creases can be provided insofar as is allowable by the braided wire mesh density and diameter.

Seam 126*c* can be formed by joining together two or more longitudinal portions of the liner 122*c*. When two such longitudinal portions are joined together, they are generally opposite to each other. When three such longitudinal portions are joined together, they are approximately 120° from each other along the circumference of the liner 122*c*, and three legs are formed. When four such longitudinal portions are joined together, for example, they are spaced approximately 90° apart.

Whatever the number of indents or seams, the deformation of the braided tubular body reduces the cross-sectional area from that of the main trunk body to that of each branched area. The total cross-sectional area of the branching tubular bodies should be equal to or greater than 40% of the cross-sectional area of the main trunk body. Preferably, this area should be greater than about 70% in order to prevent any significant pressure differences along the device once deployed and implanted. For example, in a typical human, the cross-sectional area of the abdominal aorta is reduced by only about 20% when opening into the common iliac arteries.

FIG. 26 illustrates a fixture suitable for use in forming the indent or indents as permanent deformations of the braided mesh cylinder which is the tubular supportive component for this embodiment. Fixture 131 in the configuration as illustrated is used for shaping a symmetrical bifurcated design. The braided cylinder is longitudinally compressed and placed over the mandrel 132, this placement being generally shown in FIG. 27. End caps 133, 134 lock the tubular supportive component 121 in its compressed state. Same is then placed into the fixture 131, as generally shown in FIG. 26. Slits 135 are positioned parallel to the longitudinal axis and on opposite sides. This permits the slipping of blades 136, 137 into the fixture 131 and thus into engagement with the tubular supportive component. Edges 138, 139 of the blades then engage and crease the tubular supportive component 121 between the blade edges 138, 139 and the troughs 141, 142 of the mandrel 132.

It will be appreciated that the length of the blade edges 138, 139 can be varied in order to create a desired length of deformation on the main body of the trunk component. In addition, branching areas thus formed can be made of different sizes by varying the size of the individual cylindrical components of the mandrel 132 so they are not

identical as shown in FIG. 26. A larger sized mandrel cylinder will result in the formation of a larger trunk component leg 109, 113. This would typically also include shifting the location of the slits 135 so that the plane of blade insertion will line up with the troughs. It will be appreciated that the trifurcated arrangement is achieved by a three-component mandrel and three slits and blades that are 120° apart. Similarly, a four-branched structure would include four of each features, spaced 90° apart.

In a preferred arrangement for this embodiment, the thus deformed braided tubular supportive component is chemically and heat processed in order to set the desired diameter and mechanical properties of the main body. Once this flexible metallic stent with conformed shape is thus prepared, it is preferably lined as discussed elsewhere herein. It will be noted that the illustrated tubular braided mesh has a main cross-sectional area and has an outward flair at both ends. The braided structure is advantageously accommodated by the serrated structure of the blade edges 138, 139 in that the wire elements of the braid are grasped and secured at the ends of the bifurcation.

The expandable supportive graft of the present invention is capable of being tailored to meet specific needs, depending upon the particular defect or disease being addressed, such as occlusion, stenosis, aneurysm, arteriovenosis fistula, trauma and the like, as well as upon the anatomy of the vessel. For example, it can be desirable to have the support component of the expandable supportive graft at locations other than throughout the entirety of the graft as specifically illustrated in FIGS. 1 through 4 hereof. The bifurcated graft of FIGS. 7 and 8 shows some separation along the support component, such as between the trunk 61 and the branches 62, 63. It is also possible, with the grafts in accordance with the present invention, to provide an expandable graft having its supportive property emanating from one or more support components, while thereby providing an adjoining graft cylindrical portion which is supported primarily by its close proximity to a support component which can be presented at one end, both ends, or spaced along the expandable supportive graft in accordance with invention.

Such a structure is generally illustrated in FIG. 5, wherein an adjoining graft cylindrical portion 71 is positioned between a first support component 72 and another or second support component 73. The expandable supportive graft in accordance with the present invention provides the tailorability advantage of being able to vary within a single graft the configuration, structure and properties of the support component or components of the graft. These various properties allow the expandable supportive graft to be tailored in accordance with particular needs of the disease, defect or damage being treated. For example, support may be particularly desirable at one location being treated, while a less rigid supportive area is needed at another, generally adjoining location. By the expandable supportive graft in accordance with this invention, a single graft can be deployed in order to effect two or more different functions. By achieving multiple support and/or repair functions with a single device, possible trauma to the patient is minimized by reducing the number of transluminal passages needed to address a situation that could otherwise require separate stents or grafts, each of which is separately deployed or implanted.

With further reference to the tailorability aspects, the present invention reduces the risk of compromising the patency of the passageways being treated. This is particularly true in treating lesions at or near vascular bifurcations, branches and/or anastomoses. Typical difficulties which can

be avoided by the present invention include displacing of diseased tissue, vessel spasm, dissection with or without intimal flaps, thrombosis, embolism, and the like. Another suitable use is for dilating and/or supporting vascular graft bifurcations and the like. Additionally, lesions affecting vascular trifurcations can be treated. Also treatable are obstructed openings characterized by exaggerated cicatrization, abnormal cellular growth (subintimal fibromuscular hyperplasia and the like) or arterial or venous stenosis. Moreover, these supportive grafts can be used to reinforce vascular walls, weakened by pathological processes, for example, by dissection, as in the case of aneurysms. The grafts can also obliterate congenital or acquired arteriovenous communications, and they can be applied in intrahepatic portal-caval shunts. The grafts also can maintain biological pathways open, such as the digestive, biliary, pancreatic and urinary tracts, and they help to limit the intraluminal growth of pathological processes such as fibrosis or cancer.

EXAMPLE I

This example illustrates the formation of a branched expandable supportive endoluminal graft having an expanded internal diameter of 10 mm and which is bifurcated to accommodate two endoluminal supportive graft legs of 5 to 7 mm in diameter. A liner of non-woven polycarbonate urethane (Corethane®) was spun by winding over a mandrel, generally in accordance with U.S. Pat. No. 4,475,972. In this instance, the liner consisted of approximately 400 layers of fibers. A bifurcated braided mesh tubular supportive component made in a fixture as illustrated in FIG. 26 was spray coated using a dilute solution of polycarbonate urethane having a hardness grade and a melting point lower than that used to spin the liner. It was allowed to dry with warm air. Several spray coats allow for the formation of an adhesive layer.

The previously prepared polycarbonate urethane liner was cut to length and placed inside the adhesive-coated bifurcated braided mesh and seated to closely fit the bifurcated braided mesh. A mandrel having a shape similar to the inner configuration of the bifurcated mesh was inserted from one end to act as a support. Shrink tubing was slipped over portions of this assembly. This assembly was heated to the melting point of the polycarbonate urethane adhesive while allowing the shrink tubing to heat shrink and compress the braided mesh against the liner which is supported by the shaped mandrel. After cooling, the shrink tubing was removed and the mandrel slipped out, leaving a completed trunk component as described herein.

The two endoluminal tubular expandable supportive graft leg components are prepared in accordance with a similar procedure which is simpler because of the cylindrical shape of these components.

EXAMPLE II

The procedure of Example I is substantially repeated, except the liner is a double tricot polyester mesh net. In a similar arrangement, a trunk component of the same structure was formed, except prior to insertion of the supporting mandrel, a second, innermost liner of polycarbonate urethane is positioned in order to provide a double-lined branched component.

EXAMPLE III

The procedures of Example I and of Example II are generally followed, except here the expanded inner diameter

of the trunk component is 25 mm, and the cylindrical leg endoluminal grafts are 12–15 mm in diameter.

EXAMPLE IV

A branched vascular expandable supportive endoluminal graft was made using a 16 mm diameter, 12 cm long Wallstent® device as the support component in the following manner. A grounded 16 mm mandrel was rotated on a spinning machine at 500 RPM, and a spinnerette with 30 orifices was reciprocated along the axis of the mandrel at 13.8 inches/second while applying 40,000 volts to the spinnerette. Polycarbonate urethane, in dimethyl acetamide solution (45% solids) was extruded from the spinnerette at 0.123 ml/min, the fibers coming onto the mandrel in random fashion to form a mat-like structure having randomly shaped pores. The environment in the spinning chamber was controlled such that sufficient solvent from the urethane solution evaporated off during spinning to enable the fibers to be bond to underlying fibers during each transverse of the spinnerette. After 300 passes of the spinnerette, the spinning procedure was stopped and the mandrel with the spun polycarbonate urethane mat was removed from the machine and cured at 110° C. for 16 hours. The tubular mat still on the mandrel was trimmed to the appropriate size and the Wallstent® device was sheathed over the mesh and the ends taped down. Another 10 passes of polycarbonate urethane were spun over the Wallstent® device, and the fibers, while still wet, are immediately pressed through the interstices of the Wallstent® device with a silicone rubber sponge at selected longitudinal locations, such that the fibers bond to the underlying fibers of the urethane mat, thereby capturing the Wallstent® device within the urethane wall along those longitudinal locations. The assembly is then cured for an additional 3 hours at 110° C., after which the assembly is removed from the mandrel. The expandable supportive endoluminal graft formed in this manner had the bulk of the urethane mesh on the inside of the stent. The longitudinal locations which are not secured to the stent are joined together to form a seam to define two legs as generally shown in FIG. 31.

EXAMPLE V

A branched aortic expandable supportive endoluminal graft is made in the following manner. An aortic trunk supportive endoluminal graft is fabricated using a 16 mm diameter, 12 cm long support component. First, a 16 mm mandrel is rotated on a spinning machine at 500 rpm, and a spinnerette with 30 orifices reciprocated along the axis of the mandrel at 13.8 inches/second. Polycarbonate urethane, in dimethyl acetamide solution (45% solids) is extruded from the spinnerette at 0.123 ml/min and wound onto the rotating mandrel such that the fibers form a 50° pitch angle in relation to the axis of the mandrel. The environment in the spinning chamber is controlled such that sufficient solvent from the urethane solution evaporates off during spinning to enable the fibers to bond to underlying fibers during each transverse of the spinnerette. The formed spun polycarbonate urethane mesh has a length of about 16 cm, is removed from the machine and is cured at 110° C. for 16 hours. The support component is sheathed over the mesh still on the mandrel. Another 10 passes of polycarbonate urethane are spun over the tubular mesh, support component, but not over the 4 cm excess length of the internal tubular mesh, and the fibers, while still wet, are immediately pressed through the interstices of the support component with a silicone rubber sponge, such that the fibers bonded to the underlying fibers

of the urethane mesh, thereby capturing the support component within the urethane wall. The assembly is then cured for an additional 3 hours at 110° C., after which the assembly is removed from the mandrel. The supportive endoluminal graft formed in this manner has fiber diameters of 10 to 20μ and pore sizes ranging from 10 to 60μ.

The length of the tubular mesh which is spaced about 4 cm from each side of the assembled endoprosthesis is then slit and sewn down the center such that the tube is branched into two smaller tubes along about 8 cm of the longitudinal central length of the tubular mesh.

The aortic trunk endoprosthesis is pulled down and sheathed on an introducer catheter, maneuvered into the aorta of a dog, via the dog's femoral artery for deployment in the abdominal aorta. Two smaller stents, of 8 mm diameter, are also pulled down onto introducer catheters and maneuvered, through each femoral artery for deployment into the seam-defined two smaller tubes or "legs" of the aortic trunk. The resultant branched endoprosthesis is for limiting further dilation of an abdominal-iliac aneurysm.

EXAMPLE VI

A branched expandable supportive endoluminal graft is provided for deployment within and repair of aorto-iliac aneurysms. A generally tubular metallic stent of the self-expandable type is adhered to the outside of a porous spun liner as follows. The graft is wound or spun from filaments deposited onto a rotating mandrel in order to form a cylindrical graft having crossing strands generally adhered together. The resulting inner liner, after it is dried, has a stent component placed over it. Then, an area of the stent is masked, such as with a piece of tape, at the location where an internal seam is to be positioned in the trunk component of the supportive endoluminal graft. The masking can take on a shape on the order of the triangular areas illustrated in FIG. 32, with the upper apex forming the upper "crotch" of the seam, and the lower apex forming the lower "crotch" of the seam. Additional fibers are then spun over the entire stent and pressed through the stent intersticies to be certain that the stent is secured to the liner. This continues until all areas of the stent are well-bonded except for the masked areas. After removal of the mandrel and of the masking material, the initially formed inner liner is free to be pinched along its length and sutured, sewed and/or glued and the like to form two distinct leg portions and a trunk portion of the liner. The resulting trunk component is as generally shown in FIGS. 31 and 32.

The leg components of the branched supportive endoluminal graft in accordance with this Example are individually made in a similar manner. The liner is formed by spinning compliant fibers over a rotating mandrel, a tubular stent component is positioned thereover and secured in place, and additional fibers are wound with the rotating mandrel. The stent is thus encapsulated between the liner fibers and the cover fibers, preferably with the aid of a soft roller or sponge to force the cover strands into the intersticies of the stent component and securement to the underlying liner fibers. After removal from the mandrel, the resulting tubular supported graft component, suitable for use as both the iliac components, is trimmed to proper length.

EXAMPLE VII

A branched aortic expandable supportive endoluminal graft was made using a liner of polycarbonate urethane. The cylindrical liner was flattened, and a longitudinal seam was formed by heat sealing together the flattened opposing

portions along a thus formed seal line. A self-expanding cylindrical stent-like support component was coated on at least its inside surface with a heat-activated adhesive. The seamed liner was inserted into the stent-like support component, and the liner was inflated until the two non-seamed portions of the liner and the radially extending portions of the seamed portion of the liner engaged the inner surface of the support component. Then, this assembly with the inflated liner was placed into an oven to activate the adhesive whereby, upon subsequent cooling, the seamed liner was secured to the support component to form a branched trunk component as shown in FIGS. 31 and 32. In this example, the inflation of the liner was carried out by packing the seamed liner with salt crystals so the liner stretches in place and until adhesion between the liner and the support component had occurred.

EXAMPLE VIII

A branched trunk component is prepared as described in Example VII, except the liner inflation is carried out by expanding balloon activity, and the seam is formed by suturing. Because the branched trunk component will elongate when collapsed for entry into the delivery tool, the suturing allows for longitudinal expansion and contraction back down to the as-manufactured seam length. Such suturing is achieved by using a zig-zag stitch pattern.

EXAMPLE IX

Another branched trunk component is made as described in Example VIII, except the liner inflation is carried out by a mandrel, and the sutured seam is formed with a polyurethane compliant suture material.

It will be understood that the embodiments of the present invention which have been described are illustrative of some of the applications of the principles of the present invention. Various modifications may be made by those skilled in the art without departing from the true spirit and scope of the invention.

I claim:

1. A multiple-component branched expandable supportive endoluminal graft comprising:

a plurality of expandable supportive endoluminal components which are deployed individually at a selected location within a body vessel, each said supportive endoluminal graft component being radially compressible for endoluminal insertion and radially expandable for deployment at a desired location within a body vessel;

one of said expandable supportive endoluminal components is a trunk component, said trunk component including a tubular supporting member and a trunk liner positioned along said tubular supporting member, said trunk liner having a generally cylindrical upper body portion, at least two leg portions, and a generally cylindrical lower body portion, each said leg portion defining a leg opening into said upper body portion and another leg opening into said lower body portion;

at least one other of said expandable supportive endoluminal components is a generally cylindrical supportive leg component; and

said generally cylindrical supportive leg component and one of said leg portions of the trunk component, when said leg component and trunk component are deployed within the body vessel, are telescopically positioned with respect to each other.

2. The supportive endoluminal graft in accordance with claim 1, wherein said generally cylindrical supportive leg component has an end portion which, when deployed, is positioned within one said leg opening of the trunk component.

3. The supportive endoluminal graft in accordance with claim 1, wherein said plurality of expandable supportive endoluminal components are self-expanding.

4. The supportive endoluminal graft in accordance with claim 1, wherein said plurality of expandable supportive endoluminal components are deployed by a radially expandable device.

5. The supportive endoluminal graft in accordance with claim 1, wherein said generally cylindrical supportive component includes a generally cylindrical supporting member and a generally cylindrical liner secured therealong.

6. The supportive endoluminal graft in accordance with claim 1, wherein said trunk liner is a stretchable wall of essentially inert biocompatible material, said stretchable wall being attached to a portion of the internal surface of the trunk component tubular supporting member, said stretchable wall having a diameter size that expands with said trunk component tubular supporting member.

7. The supportive endoluminal graft in accordance with claim 5, wherein said liner of the generally cylindrical supportive leg component is a stretchable wall of essentially inert biocompatible material, said stretchable wall being applied onto at least the internal surface of the generally cylindrical tubular supporting member of the leg component.

8. The supportive endoluminal graft in accordance with claim 1, wherein said at least two leg portions of the trunk liner are partially defined by a longitudinal seam which extends generally between said generally cylindrical upper and lower body portions of the trunk liner.

9. The supportive endoluminal graft in accordance with claim 8, wherein said leg portions are further defined by portions of the trunk liner which are secured to the tubular supporting member at a location spaced radially from said longitudinal seam.

10. The supportive endoluminal graft in accordance with claim 1, wherein said leg portions of the trunk liner are longitudinally generally coextensive with a central longitudinal portion of said tubular supporting member of the trunk component.

11. The supportive endoluminal graft in accordance with claim 10, wherein an outside section of each of said leg portions of the trunk liner is secured to said tubular supporting member, while inside sections of each of said leg portions are secured to each other along an internal seam.

12. The supportive endoluminal graft in accordance with claim 1, wherein said generally cylindrical supportive leg component, when deployed, is telescopically slidably positioned within one of said leg portions of the trunk component.

13. The supportive endoluminal graft in accordance with claim 5, wherein said liner of the leg component and said trunk liner are each a stretchable wall made from a porous elastomeric material that provides a structure which allows normal cellular invasion thereinto from the body vessel when implanted therewithin.

14. The supportive endoluminal graft in accordance with claim 13, wherein said porous elastomeric material of each stretchable wall is an elastomeric polymer.

15. The supportive endoluminal graft in accordance with claim 13, wherein said porous elastomeric material of said stretchable wall is a polycarbonate urethane.

16. The supportive endoluminal graft in accordance with claim 13, wherein said porous elastomeric material is coated with a thin layer of silicone rubber.

17. The supportive endoluminal graft in accordance with claim 5, wherein said trunk liner and said liner of the leg component are each a stretchable wall along the internal surface and the external surface of each tubular supporting component.

18. The supportive endoluminal graft in accordance with claim 1, wherein an exposed longitudinal end of said tubular supporting member extends longitudinally beyond and is not completely covered by said liner.

19. The supportive endoluminal graft in accordance with claim 1, wherein said tubular supporting component includes a plurality of wire strands with open areas therebetween.

20. The supportive endoluminal graft in accordance with claim 19, wherein said wire strands of the tubular supporting component are generally sinusoidally configured wire that is helically wound into the tubular supporting component, said wire defining therebetween said open areas of the tubular supporting component.

21. The supportive endoluminal graft in accordance with claim 19, wherein said wire strands of the tubular supporting component are shaped as intersecting elongated lengths integral with each other and defining said openings therebetween to form a mesh-shaped tubular supporting component.

22. The supportive endoluminal graft in accordance with claim 1, wherein said trunk component includes a projecting securement member.

23. A multiple-component branching expandable supportive endoluminal graft comprising:

a plurality of expandable supportive endoluminal graft components which are deployed individually at a selected location within a body vessel, each said supportive endoluminal graft component being radially compressible and radially expansible;

one of said expandable supportive endoluminal graft components being a trunk component having a longitudinal axis, an internal liner including a seam disposed generally along the longitudinal axis, and an external surface which is generally cylindrical and spaced outwardly from said internal liner, said trunk component having a plurality of legs defined in part by said seam, said trunk component further having two generally cylindrical body portions which flank said seam and which extend in opposite directions from said legs;

at least one other of said expandable supportive endoluminal graft components being a generally cylindrical supportive leg component;

said trunk component liner being a stretchable wall of essentially inert biocompatible material, said stretchable wall being applied onto an internal surface of a tubular supporting component; and

each said leg is sized and shaped to receive said generally cylindrical supportive leg component.

24. The branching graft according to claim 23, wherein said trunk component has a network of land areas with open areas defined therebetween.

25. A method for making a multi-component bifurcating expandable supportive endoluminal graft, comprising the steps of:

providing a generally tubular self-supporting member;

providing a generally cylindrical liner made of flexible material, and flattening said liner so opposing surfaces engage each other;

forming a longitudinal seam within the thus flattened liner in order to secure opposing longitudinal portions of the liner to each other;

inserting the thus seamed liner within the generally tubular self-supporting member;

inflating the seamed liner while within the self-supporting member until radially extending surfaces of the liner engage an inner surface of the tubular self-support member; and

securing said liner radially extending surfaces onto the thus engaged inner surface of the tubular self-supporting member in order to thereby assemble a branched trunk component.

26. The method of claim 25 further including providing a further expandable supportive endoluminal graft component by providing a generally cylindrical supportive leg compo-

nent which is sized to be telescopically assembled with one of the leg portions of the branched trunk component.

27. The method of claim 25, wherein said inflating step includes filling the seamed liner with elutable materials.

28. The method in accordance with claim 25, wherein said inflating step includes inserting an expandable elongated tool into the seamed liner and expanding same so as to dilate the seamed liner into engagement with the self-supporting member.

29. The method in accordance with claim 25, wherein said step of forming a longitudinal seam includes applying heat along the longitudinal seam location.

30. The method in accordance with claim 25, wherein said step of forming a longitudinal seam includes suturing.

[* * * * *]

31. A method for manufacturing a multi-lumen tubular supporting component for an endoluminal graft, comprising the steps of:

forming a tubular support component; and

crimping at least one longitudinal portion of said tubular supporting component to form at least one longitudinally disposed indent therein to provide a multiple-lumen portion of said tubular supportive component.

32. The method of claim 31 wherein one longitudinally disposed indent is formed to provide a double lumen portion of said tubular supportive component.

33. The method of claim 31 wherein two parallel, longitudinally disposed, not diametrically opposed, indents are formed to provide a triple lumen portion of said tubular supportive component.

34. The method of claim 31 wherein two longitudinally disposed, diametrically opposed, indents are formed to provide a double lumen portion of said tubular supportive component.

35. The method of claim 31 wherein three longitudinally disposed indents are formed to provide a quadruple lumen portion of said tubular supportive component.

36. A multi-component branching expandable supportive endoluminal graft comprising:

a plurality of expandable supportive endoluminal components adapted to be individually deployed at a selected location within a body vessel, each said supportive endoluminal graft component being radially compressible for endoluminal insertion and radially expandable for deployment at a desired location within a body vessel;

one of said expandable supportive endoluminal components is a trunk component, said trunk component being generally tubular and having a first trunk portion with a given diameter and a second trunk portion including two diametrically opposed,

longitudinally disposed, indents generally defining two parallel, supportive lumens, each with a diameter less than said given diameter;

a trunk liner disposed within said trunk component, said trunk liner having a generally cylindrical body portion and two leg liner portions, each said leg liner portion defining a leg opening, wherein each of said leg liner portions is disposed within respective parallel, supportive lumens of said trunk component, and the generally cylindrical body portion of said liner is disposed within a non-indented portion of said generally cylindrical trunk component; and

at least one other of said expandable supportive endoluminal components is a supportive leg component;

wherein an end portion of said supportive leg component, when said supportive leg component and said trunk component are deployed within the body vessel, is positioned within a leg opening of said liner.

37. The supportive endoluminal graft of claim 36, wherein said end portion of said supportive leg component, when deployed, is telescopically positioned within one of said parallel supportive lumens of the trunk component.

38. The supportive endoluminal graft of claim 36 or claim 37, wherein said plurality of expandable supportive endoluminal components are self-expanding.

39. The supportive endoluminal graft of claim 36 or 37, wherein said liner portions are attached to one another along a line between said diametrically opposed indents.

40. A multi-component bifurcating expandable supportive endoluminal graft comprising:

a plurality of expandable supportive endoluminal components adapted to be individually deployed at a selected location within a body vessel, each said supportive endoluminal graft component being radially compressible for endoluminal insertion and radially expandable for deployment at a desired location within a body vessel;

one of said expandable supportive endoluminal components is a trunk component, said trunk component generally surrounding a trunk liner positioned within said trunk component, said trunk liner having a generally cylindrical body portion and

two leg portions, each said leg portion defining a leg opening, wherein the generally cylindrical body portion of said liner and portions of said leg portions abut said tubular supporting member and are secured to said tubular supporting member, and portions of said leg portions not abutting said tubular supporting member abut one another and are secured to one another;

at least one other of said expandable supportive endoluminal components is a generally cylindrical supportive leg component; and

said generally cylindrical supportive leg component and one of said leg portions of said liner, when said leg component and trunk component are deployed within the body vessel, are telescopically positioned with respect to each other.

41. The supportive endoluminal graft of claim 40, wherein said generally cylindrical supportive leg component has an end portion which, when deployed, is positioned within a said leg opening of the trunk liner.

42. The supportive endoluminal graft of claim 40 or claim 41, wherein said plurality of expandable supportive endoluminal components are self-expanding.

* * * * * *

[57] ABSTRACT

An endoluminal graft which is both expandable and supportive is provided in a form suitable for use in a branched body vessel location. The graft expands between a first diameter and a second, larger diameter. The support component is an expandable stent endoprosthesis. A liner is applied to the endoprosthesis in the form of a compliant wall material that is porous and biocompatible in order to allow normal cellular invasion upon implantation, without stenosis, when the expandable and supportive graft is at its second diameter. The supportive endoluminal graft is preferably provided as a plurality of components that are deployed separately at the branching body vessel location, one of which has a longitudinal seam defining leg portions within which the other components fit in a telescoping manner.

30 Claims, 6 Drawing Sheets

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Reissue Application No.:	:
Filed: Herewith	:
Applicants: Leonard Pinchuk, Yasushi Kato Rylser Alcime	: :
Patent No.: 5,855,598	:
Issued: January 5, 1999	:
For: EXPANDABLE SUPPORTIVE BRANCHED ENDOLUMINAL GRAFTS	: :

CONSENT OF ASSIGNEE TO REISSUE

Assistant Commissioner for Patents
Box Reissue Application
Washington, D.C. 20231

S I R :

Corvita Corporation is the assignee of the entire and undivided interest in the above-mentioned Letters Patent as evidenced by the assignment information filed herewith. The assignment from Leonard Pinchuk to Corvita Corporation was recorded in the U.S. Patent and Trademark Office at reel 8762, frame 0184. A copy of the executed assignments to Corvita Corporation from inventors Yasushi Kato and Rysler Alcime is attached. These assignments will be recorded upon acceptance of the Petition For Correction of Inventorship of Patent pursuant to 37 C.F.R. §1.324, filed for U.S. Patent No. 5,855,598, the patent for which reissue is sought.

Corvita Corporation hereby consents to this application for reissue. The undersigned is empowered to sign this statement on behalf of the assignee, as evidenced by the attached Power of Attorney. More

generally, Corvita Corporation is owned by Boston Scientific Corporation.

Corvita Corporation

Dated: 8/02/00

By: _____
David L. Cavanaugh

Title: Patent Attorney
Boston Scientific Corporation

BSI-430US8 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Leonard Pinchuk : Art Unit: 3738

Patent No.: Re Issue Application of Patent No. 5,855,598 : Examiner: M. Milano

Issued: January 5, 1999

For: EXPANDABLE SUPPORTIVE BRANCHED ENDOLUMINAL GRAFTS

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

S I R :

Pursuant to 37 C.F.R. §§ 1.97 and 1.98 and to the duty of disclosure set forth in 37 C.F.R. § 1.56, the Examiner in charge of the above-identified application is requested to consider and make of record the references listed on the PTO 1449 (R&P) submitted herewith.

Although the information submitted herewith may be "material" to the Examiner's consideration of the subject application, this submission is not intended to constitute an admission that such information is "prior art" as to the claimed invention.

In accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

No first Official Action has yet been received and it is presumed that none has yet been mailed. No fee or certification is required. 37 C.F.R. § 1.97(b).

Respectfully submitted,

RATNER & PRESTIA

Jonathan H. Spadt, Reg. No. 45,122
Attorney for Applicant

Dated: February 23, 2001
Encls.: PTO Form 1449 (w/5 References)
Suite 301, One Westlakes, Berwyn
P.O. Box 980
Valley Forge, PA 19482-0980
(610) 407-0700

EXPRESS MAIL Mailing Label Number: EL711313216US
Date of Deposit: February 23, 2001

I hereby certify that this paper and fee are being deposited, under 37 C.F.R. § 1.10 and with sufficient postage, using the "Express Mail Post Office to Addressee" service of the United States Postal Service on the date indicated above and that the deposit is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Lisa M. Machado

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EL711313216US

FORM PTO-1449

Sheet 1 of 1

FORM PTO-1449 (Rev. 2-32) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. BSI-430US8	Patent NO 5,855,598
Information Disclosure Statement by Applicant (Use several sheets if necessary)	APPLICANT Leonard Pinchuk et al.	
	ISSUED DATE January 5, 1999	GROUP 3738

U.S. PATENT DOCUMENTS

Exmr Initial		Document Number	Date	Name	Class	Sub Class	Filing Date
		5,683,449	11/4/97	Marcade			

FOREIGN PATENT DOCUMENTS

Exmr Initial		Document Number	Date	Country	Class	Sub Class	Translation YES	NO
		EP 0551179 A1	07/14/93	EPO			X	
		WO 95 13033	05/18/95	PCT			X	

OTHER DOCUMENTS

(Including Author, Title, Date, Pertinent Pages, Etc.)

		1)	European Search Report, Application No. 00303472.5 dated 08/30/2000
		2)	G. J. Wilson et al., "A Self Expanding Bifurcated Endovascular Graft for Abdominal Aortic Aneurysm Repair"; Asaio Journal, U.S. J.B. Lippincott Co., Vol. 42, No. 5, Sept. 1, 1996, pp. M386-M393

Examiner	Date Considered

Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

BSI-430US8 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Leonard Pinchuk et al.	: Art Unit:
Serial No.:	09/657,041	: Examiner:
Filed: :	September 5, 2000	:
For: :	EXPANDABLE SUPPORTIVE	:
	BRANCHED ENDOLUMINAL GRAFTS	:

STATUS REQUEST

Assistant Commissioner for Patents
Washington, D.C. 20231

S I R :

The status of the above-identified application is respectfully requested. This application was filed on (September 5, 2000) and no action has been received.

Kindly advise the undersigned of the present status of this application by checking the appropriate box below. A copy of this Status Request is enclosed with a self-addressed stamped envelope.

Application Serial No. 09/657,041 is currently

☒ Assigned to Group 3738 and awaits: REISSUE

Respectfully submitted,

Jonathan H. Spadt, Reg. No. 45,122
Attorney for Applicants

JHS/mkm
Dated: March 5, 2002
Suite 301
One Westlakes, Berwyn
P.O. Box 980
Valley Forge, PA 19482-0980
(610) 407-0700

The Assistant Commissioner for Patents is hereby authorized to charge payment to Deposit Account No. **18-0350** of any fees associated with this communication.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, with sufficient postage, in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on: March 5, 2002

Mary K. MacMillan

BSI-430US8 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Leonard Pinchuk	: Art Unit: 3738
Patent No.:	Re Issue Application of Patent No. 5,855,598	: Examiner: M. Milano
Issued:	January 5, 1999	
For:	EXPANDABLE SUPPORTIVE BRANCHED ENDOLUMINAL GRAFTS	

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

S I R :

Pursuant to 37 C.F.R. §§ 1.97 and 1.98 and to the duty of disclosure set forth in 37 C.F.R. § 1.56, the Examiner in charge of the above-identified application is requested to consider and make of record the references listed on the PTO 1449 (R&P) submitted herewith. A copy of each of the listed references is also enclosed.

Although the information submitted herewith may be "material" to the Examiner's consideration of the subject application, this submission is not intended to constitute an admission that such information is "prior art" as to the claimed invention.

In accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

No first Official Action has yet been received and it is presumed that none has yet been mailed. No fee or certification is required. 37 C.F.R. § 1.97(b).

Respectfully submitted,

Jonathan H. Spadt, Reg. No. 45,122
Attorneys for Applicant

Enclosures: PTO Form 1449
Copy of (1) References

Dated: May 28, 2002

P.O. Box 980
Valley Forge, PA 19482-0980
(610) 407-0700

The Assistant Commissioner for Patents is hereby authorized to charge payment to Deposit Account No. **18-0350** of any fees associated with this communication.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, with sufficient postage, in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on: May 28, 2002

Mary K. MacMillan

FORM PTO-1449

Sheet 1 of 1

FORM PTO-1449 (Rev. 2-32) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO.	Patent NO
Information Disclosure Statement by Applicant	BSI-430US8	5,855,598
(Use several sheets if necessary)	APPLICANT Leonard Pinchuk et al.	
	ISSUED DATE January 5, 1999	GROUP 3738

U.S. PATENT DOCUMENTS

Exmr Initial		Document Number	Date	Name	Class	Sub Class	Filing Date
		6,302,906	10/16/01	Goicoechea et al.			

FOREIGN PATENT DOCUMENTS

Exmr Initial		Document Number	Date	Country	Class	Sub Class	Translation YES	NO

OTHER DOCUMENTS

(Including Author, Title, Date, Pertinent Pages, Etc.)

Examiner	Date Considered

Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

USPTO Form 1449 [R&P]

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No:	09/657,041
Applicant:	Leonard Pinchuk et al.
Filed:	9/5/2000
Title:	Expandable Supportive Branched Endoluminal Grafts
T.C./A.U.:	3731
Examiner:	Michael H. Thaler
Confirmation No.:	9622
Docket No.:	BSI-430US8

AMENDMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Responsive to the Office Action dated July 2, 2003, please amend the above-identified application as follows:

☒ **Amendments to the Claims** are reflected in the listing of claims which begins on page 2 of this paper.

☒ **Amendments to the Drawings** begin on page 7 of this paper and include an attached replacement sheet(s).

☒ **Remarks/Arguments** begin on page 8 of this paper.

Amendments to the Claims: This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

1. (Original) A multiple-component branched expandable supportive endoluminal graft comprising:

a plurality of expandable supportive endoluminal components which are deployed individually at a selected location within a body vessel, each said supportive endoluminal graft component being radially compressible for endoluminal insertion and radially expandable for deployment at a desired location within a body vessel;

one of said expandable supportive endoluminal components is a trunk component, said trunk component including a tubular supporting member and a trunk liner positioned along said tubular supporting member, said trunk liner having a generally cylindrical upper body portion, at least two leg portions, and a generally cylindrical lower body portion, each said leg portion defining a leg opening into said upper body portion and another leg opening into said lower body portion;

at least one other of said expandable supportive endoluminal components is a generally cylindrical supportive leg component; and

said generally cylindrical supportive leg component and one of said leg portions of the trunk component, when said leg component and trunk component are deployed within the body vessel, are telescopically positioned with respect to each other.

2. (Original) The supportive endoluminal graft in accordance with claim 1, wherein said generally cylindrical supportive leg component has an end portion which, when deployed, is positioned within one said leg opening of the trunk component.

3. (Original) The supportive endoluminal graft in accordance with claim 1, wherein said plurality of expandable supportive endoluminal components are self-expanding.

4. (Original) The supportive endoluminal graft in accordance with claim 1, wherein said plurality of expandable supportive endoluminal components are deployed by a radially expandable device.

5. (Original) The supportive endoluminal graft in accordance with claim 1, wherein said generally cylindrical supportive component includes a generally cylindrical supporting member and a generally cylindrical liner secured therealong.

6. (Original) The supportive endoluminal graft in accordance with claim 1, wherein said trunk liner is a stretchable wall of essentially inert biocompatible material, said stretchable wall being attached to a portion of the internal surface of the trunk component tubular supporting member, said stretchable wall having a diameter size that expands with said trunk component tubular supporting member.

7. (Original) The supportive endoluminal graft in accordance with claim 5, wherein said liner of the generally cylindrical supportive leg component is a stretchable wall of essentially inert

biocompatible material, said stretchable wall being applied onto at least the internal surface of the generally cylindrical tubular supporting member of the leg component.

8. (Original) The supportive endoluminal graft in accordance with claim 1, wherein said at least two leg portions of the trunk liner are partially defined by a longitudinal seam which extends generally between said generally cylindrical upper and lower body portions of the trunk liner.

9. (Original) The supportive endoluminal graft in accordance with claim 8, wherein said leg portions are further defined by portions of the trunk liner which are secured to the tubular supporting member at a location spaced radially from said longitudinal seam.

10. (Original) The supportive endoluminal graft in accordance with claim 1, wherein said leg portions of the trunk liner are longitudinally generally coextensive with a central longitudinal portion of said tubular supporting member of the trunk component.

11. (Original) The supportive endoluminal graft in accordance with claim 10, wherein an outside section of each of said leg portions of the trunk liner is secured to said tubular supporting member, while inside sections of each of said leg portions are secured to each other along an internal seam.

12. (Original) The supportive endoluminal graft in accordance with claim 1, wherein said generally cylindrical supportive leg component, when deployed, is telescopically slidably positioned within one of said leg portions of the trunk component.

13. (Original) The supportive endoluminal graft in accordance with claim 5, wherein said liner of the leg component and said trunk liner are each a stretchable wall made from a porous elastomeric material that provides a structure which allows normal cellular invasion thereinto from the body vessel when implanted therewithin.

14. (Original) The supportive endoluminal graft in accordance with claim 13, wherein said porous elastomeric material of each stretchable wall is an elastomeric polymer.

15. (Original) The supportive endoluminal graft in accordance with claim 13, wherein said porous elastomeric material of said stretchable wall is a polycarbonate urethane.

16. (Original) The supportive endoluminal graft in accordance with claim 13, wherein said porous elastomeric material is coated with a thin layer of silicone rubber.

17. (Original) The supportive endoluminal graft in accordance with claim 5, wherein said trunk liner and said liner of the leg component are each a stretchable wall along the internal surface and the external surface of each tubular supporting component.

18. (Original) The supportive endoluminal graft in accordance with claim 1, wherein an exposed longitudinal end of said tubular supporting member extends longitudinally beyond and is not completely covered by said liner.

19. (Original) The supportive endoluminal graft in accordance with claim 1, wherein said tubular supporting component includes a plurality of wire strands with open areas therebetween.

20. (Original) The supportive endoluminal graft in accordance with claim 19, wherein said wire strands of the tubular supporting component are generally sinusoidally configured wire that is helically wound into the tubular supporting component, said wire defining therebetween said open areas of the tubular supporting component.

21. (Original) The supportive endoluminal graft in accordance with claim 19, wherein said wire strands of the tubular supporting component are shaped as intersecting elongated lengths integral with each other and defining said openings therebetween to form a mesh-shaped tubular supporting component.

22. (Original) The supportive endoluminal graft in accordance with claim 1, wherein said trunk component includes a projecting securement member.

23. (Original) A multiple-component branching expandable supportive endoluminal graft comprising:

a plurality of expandable supportive endoluminal graft components which are deployed individually at a selected location within a body vessel, each said supportive endoluminal graft component being radially compressible and radially expansible;

one of said expandable supportive endoluminal graft components being a trunk component having a longitudinal axis, an internal liner including a seam disposed generally along the longitudinal axis, and an external surface which is generally cylindrical and spaced outwardly from said internal liner, said trunk component having a plurality of legs defined in part by said seam, said trunk component further having two generally cylindrical body portions which flank said seam and which extend in opposite directions from said legs;

at least one other of said expandable supportive endoluminal graft components being a generally cylindrical supportive leg component;

said trunk component liner being a stretchable wall of essentially inert biocompatible material, said stretchable wall being applied onto an internal surface of a tubular supporting component; and

each said leg is sized and shaped to receive said generally cylindrical supportive leg component.

24. (Original) The branching graft according to claim 23, wherein said trunk component has a network of land areas with open areas defined therebetween.

25. (Original) A method for making a multi-component bifurcating expandable supportive endoluminal graft, comprising the steps of:

providing a generally tubular self-supporting member;

providing a generally cylindrical liner made of flexible material, and flattening said liner so opposing surfaces engage each other;

forming a longitudinal seam within the thus flattened liner in order to secure opposing longitudinal portions of the liner to each other;

inserting the thus seamed liner within the generally tubular self-supporting member;

inflating the seamed liner while within the self-supporting member until radially extending surfaces of the liner engage an inner surface of the tubular self-support member; and

securing said liner radially extending surfaces onto the thus engaged inner surface of the tubular self-supporting member in order to thereby assemble a branched trunk component.

26. (Original) The method of claim 25 further including providing a further expandable supportive endoluminal graft component by providing a generally cylindrical supportive leg component which is sized to be telescopically assembled with one of the leg portions of the branched trunk component.

27. (Original) The method of claim 25, wherein said inflating step includes filling the seamed liner with elutable materials.

28. (Original) The method in accordance with claim 25, wherein said inflating step includes inserting an expandable elongated tool into the seamed liner and expanding same so as to dilate the seamed liner into engagement with the self-supporting member.

29. (Original) The method in accordance with claim 25, wherein said step of forming a longitudinal seam includes applying heat along the longitudinal seam location.

30. (Original) The method in accordance with claim 25, wherein said step of forming a longitudinal seam includes suturing.

31-39 (Cancel)

40. (Currently Amended) A multi-component bifurcating expandable supportive endoluminal graft comprising:

a plurality of expandable supportive endoluminal components adapted to be individually deployed at a selected location within a body vessel, each said supportive endoluminal graft component being radially compressible for endoluminal insertion and radially expandable for deployment at a desired location within a body vessel;

one of said expandable supportive endoluminal components is a trunk component, said trunk component generally surrounding a trunk liner positioned within said trunk component, said trunk liner having a generally cylindrical body portion and two leg portions, each said leg portion defining a leg opening, wherein the generally cylindrical body portion of said liner and portions of said leg portions abut said trunk component ~~tubular supporting member~~ and are secured to said trunk component ~~tubular supporting member~~, and portions of said leg portions not abutting said trunk component ~~tubular supporting member~~ abut one another and are secured to one another;

at least one other of said expandable supportive endoluminal components is a generally cylindrical supportive leg component; and

said generally cylindrical supportive leg component and one of said leg portions of said liner, when said leg component and trunk component are deployed within the body vessel, are telescopically positioned with respect to each other.

41. (Previously Presented) The supportive endoluminal graft of claim 40, wherein said generally cylindrical supportive leg component has an end portion which, when deployed, is positioned within said leg opening of the trunk liner.

42. (Previously Presented) The supportive endoluminal graft of claim 40 or claim 41, wherein said plurality of expandable supportive endoluminal components are self-expanding.

Amendments to the Drawings:

The attached sheet of drawings includes changes to Figures 16 and 17. This sheet replaces the original sheet.

Attachment

Remarks

This is a response to the Office Action dated July 2, 2003. Preliminarily, it is noted that a number of formality objections and rejections were raised in the Office Action. These have been addressed and are discussed in detail below. The applicants wish to thank the Examiner for the courtesy shown to their representative, Jonathan H. Spadt, in a telephone conversation on July 8, 2003 during which many of these rejections and objections were discussed.

It is noted with appreciation that claims 1-30 and 40-42 are free from any rejection based upon the prior art of record. Claims 31-39 have been cancelled without prejudice and the applicants expressly reserve all rights to file one or more continuations or divisional applications directed to these claims.

Claim 40 has been amended to correct an antecedent basis issue. Withdrawal of the rejection of claims 40-42 under 35 U.S.C. § 112 is therefore respectfully requested.

It is also noted that FIGs. 16 and 17 have been amended and a replacement sheet for these figures is submitted herewith. Withdrawal of this rejection is respectfully requested.

Copy of Terminal Disclaimer

A copy of the Terminal Disclaimer filed in the prosecution of U.S. Patent No. 5,855,598 (the patent for which this Reissue is sought) is included per the Examiner's request.

Copy of Assignment

A copy of the assignment from Yasushi Kato and Rysler Alcime referred to in the Consent of Assignee document filed with this reissue application is included with this response. It is further noted that this assignment was recorded with the United States Patent and Trademark Office on September 25, 2000 at Reel 011085 Frame 0978. This confirms that Corvita Corporation owns the entire right, title, and interest to U.S. Patent No. 5,855,598, including any reissues thereof. It is further noted here that the applicant's Petition for Correction of Inventorship of Patent No. 5,855,598, which was filed along with this Reissue application, is still awaiting grant, despite the fact that it has been nearly 3 years since the

application and Petition were filed and the applicants have now received an Office Action on the merits of the present Reissue application naming the three inventors.

Information Disclosure Statement

The applicants have also included herewith a form PTO-1449 listing all of the references cited in U.S. Patent No. 5,855,598, per the request of the Examiner. It is noted, however, that the applicants do not believe that any certification or fee is necessary because no IDS or 1449 is necessary. In the event the PTO disagrees, however, an authorization to charge the deposit account accompanies the IDS.

Certificate of Correction

Corrections made in the Certificate of Correction after issuance of U.S. Patent No. 5,855,598 are also made herein without bracketing or underlining as requested by the Examiner. A copy of the Certificate of Correction is enclosed for the Examiner's convenience. Substitute sheets which have the corrections made are also included in accordance with a telephone conversation with the Examiner on July 8, 2003.

Supplemental Reissue Oath/Declaration

An unexecuted Supplemental Reissue Oath/Declaration is submitted herewith to further identify the at least one error which is relied upon to support the reissue application. A fully executed Supplemental Reissue Oath/Declaration will be submitted upon execution. Specifically, the Supplemental Reissue Oath/Declaration recites that, in addition to the error of not claiming all that they had a right to claim, the applicants are specifically seeking to broaden at least two aspects of the '598 patent which were unduly and erroneously narrow. The second error listed is directed to withdrawn claims 31-35. The first error listed concerns a broadening of what was originally in claim 1 of the '598 patent. Claim 40 is essentially original claim 1 but is broadening to some degree. Claim 40 recites that the trunk liner has a "generally cylindrical body portion and two leg portions" whereas the liner of claim 1 is required to have "a generally cylindrical upper body portion, at least two leg portions, and a generally cylindrical lower body portion . . . ." Claim 40 is supported in the specification at column 12, lines 11-13, where it is stated that the trunk component "includes a common trunk portion and a branched portion."

See also lines 50-54. Note also that the specification includes both the supportive component and liner as a part of the trunk component. See column 12, lines 60-62. Figures 22-25, it is noted, are only "embodiments" of this trunk which also have a "further common trunk portion located opposite the other common trunk portion," which embodiments became the basis for original claim 1.

Thus, at least one error which forms the basis of this reissue is the fact that the original attorney did not realize that the trunk liner is not required to have both upper and lower body portions that surround the leg portions. This error is corrected in the current reissue, namely in claim 40 and its dependent claims 41-42.

Although legally unnecessary, the applicants provided a second error which forms the basis of additional claims sought in this reissue in an attempt to avoid confusion in the future. This second basis of error supports the claims directed to the method of forming the bifurcation by indenting, which claims will likely be sought in a divisional reissue because the Examiner withdrew them from consideration in this reissue prosecution.

Status of the Claims and Support for the Claim Changes

The "status of the claims and support for claim changes" requirements enumerated in 37 C.F.R. § 1.173 (which were not in effect on September 5, 2000 when this application was filed) are met now with the following comments. Specifically, the claim status of each pending claim 1-30 and 40-42 is indicated on an attached sheet, with claims 31-39 indicated as cancelled without prejudice.

As to support, claims 1-30 are unchanged from issued Patent No. 5,855,598. As noted above, claims 40-42 are directed to essentially the same device as originally claimed, but claim 40 is broader than claim 1 in that Claim 40 recites that the trunk liner have a "generally cylindrical body portion and two leg portions" whereas the liner of claim 1 is required to have "a generally cylindrical upper body portion, at least two leg portions, and a generally cylindrical lower body portion . . . ." As noted above, claim 40 is supported in the specification throughout, especially at column 12, lines 11-13, where it is stated that the trunk component "includes a common trunk portion and a branched portion." See also lines 50-54. Note also that the specification includes both the supportive component and liner as a part of the trunk component. See column 12, lines 60-62.

As to the restriction requirement and the accompanying unilateral withdrawal of claims 31-39 as being directed to a "non-elected invention" despite the fact that the applicants made no such election, it is respectfully noted that these claims have been cancelled herein but that the applicants reserve all rights to file continuations and/or divisional application(s) directed to those claims, without prejudice.

Conclusion

The applicants respectfully assert that all objections and rejections have now been obviated and that all requirements and requests have been satisfied (with the exception of the Executed Supplemental Oath/Declaration which will be submitted forthwith). A notice of allowance of a Reissue Patent with claims 1-30 and 40-42 is respectfully requested.

Respectfully submitted,

Jonathan H. Spadt, Reg. No. 45,122
Attorney for Applicants

JHS/dhm

Attachments: Figures 14-17 (1 sheet)
Copy of Terminal Disclaimer
Copy of Assignment
PTO-1449
Copy of Certificate of Correction
Copy of patent columns with insertion of corrected text
Supplemental Reissue Oath/Declaration

Dated: October 1, 2003

☒ P.O. Box 980
Valley Forge, PA 19482
(610) 407-0700

☐ P.O. Box 1596
Wilmington, DE 19899
(302) 778-2600

The Commissioner for Patents is hereby authorized to charge payment to Deposit Account No. **18-0350** of any fees associated with this communication.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, with sufficient postage, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on:

October 1, 2003

Denise H Morgan

FIG.14

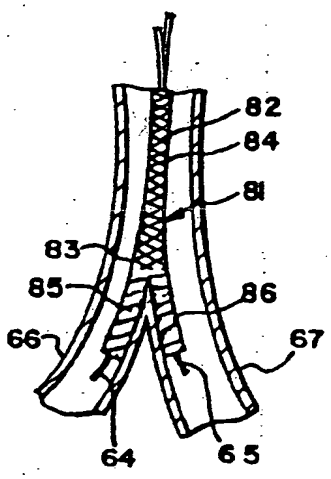


FIG.15

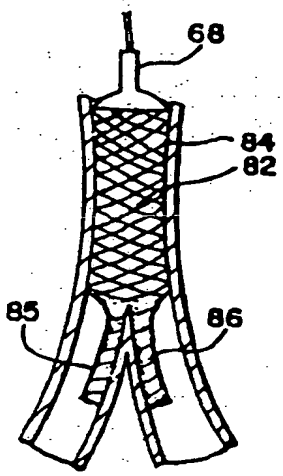


FIG.16

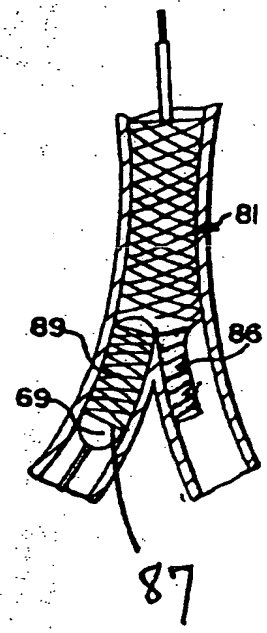
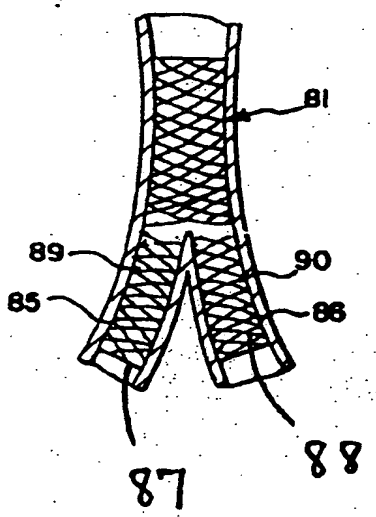


FIG.17



FILED
7/31/98

PATENT DOCKETED

Case 807P028

PC9712D

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of)
)
Leonard Pinchuk)
)
EXPANDABLE SUPPORTIVE BRANCHED)
ENDOLUMINAL GRAFTS)
)
Serial No. 08/863,964)
)
Filed: May 27, 1997)

Examiner:
Michael J. Milano

Group Art Unit: 3738

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: the Assistant Commissioner for Patents, Washington, D.C. 20231 on July 31, 1998
(Date of Deposit)

Raymond M. Mehler, Reg.No.26,306
Name of applicant, assignee or Registered Rep.

Signature 7-31-98
Date

TERMINAL DISCLAIMER

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

The undersigned, Raymond M. Mehler, represents that he is attorney of record for the above-captioned invention and application.

Disclaimant is Corvita Corporation, a corporation of the State of Florida, of Miami, Florida. Disclaimant is the assignee of the whole of this invention and of the above-identified application by Assignment recorded at Reel 8762, Frame 0184 on October 20, 1997.

The terminal part of any patent granted on the above-identified application which would extend beyond the expiration date of United States Patent No. 5,639,278, as presently shortened by any terminal disclaimer, is hereby disclaimed, except as provided below, and it is agreed that any patent so granted on the above-identified application shall be enforceable

only for and during such period that the legal title to said patent shall be the same as the legal title to United States Patent No. 5,639,278, this agreement to run with any patent granted on the above-identified application and to be binding upon the grantee, its successors or assigns.

In making this disclaimer, disclaimant does not disclaim the terminal part of any patent granted on the above-identified application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 to 156 and 173 of United States Patent No. 5,639,278, as presently shortened by any terminal disclaimer, in the event that it later: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims canceled by a reexamination certificate, is reissued in any manner, or is otherwise terminated prior to expiration of its statutory term as presently shortened by any terminal disclaimer, except for the separation of legal title stated above.

The appropriate fee to accompany this Terminal Disclaimer ($110.00) is sent herewith. The Commissioner is

hereby authorized to charge any additional fees which may be required, or to credit any overpayment, to Account No. 12-1828.

Respectfully submitted,

LOCKWOOD, ALEX, FITZGIBBON & CUMMINGS

Raymond M. Mehler
Registration No. 26,306

Three First National Plaza
Suite 1700
Chicago, Illinois 60602
(312) 782-4860

Dated: July 31, 1998

152470458

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

101467640A

NOVEMBER 08, 2000

RATNER & PRESTIA
JONATHAN H. SPADT
SUITE 301
ONE WESTLAKES, BERWYN, P.O. BOX 980
VALLEY FORGE, PA 19482-0980

UNITED STATES PATENT AND TRADEMARK OFFICE
NOTICE OF RECORDATION OF ASSIGNMENT DOCUMENT

THE ENCLOSED DOCUMENT HAS BEEN RECORDED BY THE ASSIGNMENT DIVISION OF THE U.S. PATENT AND TRADEMARK OFFICE. A COMPLETE MICROFILM COPY IS AVAILABLE AT THE ASSIGNMENT SEARCH ROOM ON THE REEL AND FRAME NUMBER REFERENCED BELOW.

PLEASE REVIEW ALL INFORMATION CONTAINED ON THIS NOTICE. THE INFORMATION CONTAINED ON THIS RECORDATION NOTICE REFLECTS THE DATA PRESENT IN THE PATENT AND TRADEMARK ASSIGNMENT SYSTEM. IF YOU SHOULD FIND ANY ERRORS OR HAVE QUESTIONS CONCERNING THIS NOTICE, YOU MAY CONTACT THE EMPLOYEE WHOSE NAME APPEARS ON THIS NOTICE AT 703-308-9723. PLEASE SEND REQUEST FOR CORRECTION TO: U.S. PATENT AND TRADEMARK OFFICE, ASSIGNMENT DIVISION, BOX ASSIGNMENTS, CG-4, 1213 JEFFERSON DAVIS HWY, SUITE 320, WASHINGTON, D.C. 20231.

RECORDATION DATE: 09/05/2000

REEL/FRAME: 011085/0978
NUMBER OF PAGES: 3

BRIEF: ASSIGNMENT OF ASSIGNOR'S INTEREST (SEE DOCUMENT FOR DETAILS).

ASSIGNOR:
PINCHUK, LEONARD

DOC DATE: 08/18/2000

ASSIGNOR:
ALCIME, RYSLER

DOC DATE: 08/18/2000

ASSIGNOR:
KATO, YASUSHI

DOC DATE: 08/18/2000

ASSIGNEE:
CORVITA CORPORATION
8210 N.W. 27TH STREET
MIAMI, FLORIDA 33122

SERIAL NUMBER: 09657041
PATENT NUMBER:

FILING DATE:
ISSUE DATE:

PEARLENE FOSTER, PARALEGAL
ASSIGNMENT DIVISION
OFFICE OF PUBLIC RECORDS

09-25-2000

101467640

PATENT ONLY

U.S. DEPARTMENT OF COMMERCE
Patent and Trademark Office

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RE ...T

...ONLY

To the Honorable Commissioner of Patents and Trademarks. Please record the attached original documents or copy thereof

1. Name of conveying party(ies):
Leonard Pinchuk; Rysler Alcime; Yasushi Kato

Additional name(s) of conveying party(ies) attached? ☐ YES ☐ NO

3. Nature of Conveyance:
- ☒ Assignment
- ☐ Merger
- ☐ Security Agreement
- ☐ Change of Name
- ☐ Correction of Assignment Recordation (previously recorded at Reel ___, Frame ___).
- ☐ Other

Execution Date: August 18, 2000

2. Name and address of receiving party(ies):
Name: Corvita Corporation
Internal Address: 8210 N.W. 27th Street
Street Address: ___
City: Miami State: FL ZIP: 33122
Additional name(s) & address(es) attached? ☐ YES ☐ NO

jc405 U.S. PTO
09/657041
09/25/00

4. Application number(s) or patent number(s): 09/657041
If this document is being filed together with a new application, the execution date of the application is: ___
A. Patent Application Number(s) ___
B. Patent Number(s) ___

Additional number(s) attached? ☐ YES ☐ NO

5. Name and address of party to whom correspondence concerning document should be mailed:
Name: Jonathan H. Spadt

Internal Address: Ratner & Prestia

Street Address: Suite 301, One Westlakes, Berwyn, P.O. Box 980
City: Valley Forge State: PA ZIP: 19482-0980

6. Total number of applications and patents involved:

7. Total fee (37 CFR 3.41): $ 40.00
- ☒ Enclosed
- ☐ Authorized to be charged to deposit account

8. Deposit account number: **18-0350**
(Attach duplicate copy of this page if paying by deposit account.)

DO NOT USE THIS SPACE

9. Statement and signature.
To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy of the original document.

Jonathan H. Spadt
Name of Person Signing

Signature

SEPT. 5, 2000
Date

45,122
Registration. No.

09657041 00000199 JJALLAH2 09/25/2000
40.00 BP
01 FC:581

Total number of pages including cover sheet, attachments, and document: 3

OMB No. 0651-0011 (exp. 4/94)

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Washington, D.C. 20231

USPTO Form 1595 [R&P]

BSI-430US8

ASSIGNMENT

WHEREAS, I, Rylser Alcime of 925 N.W. 122th Street, Miami, Florida 33161and Yasushi Kato of 311 South West, 187th Avenue, Pembroke Pines, FL 33029, (hereinafter referred to as "**ASSIGNOR**") have made an invention entitled EXPANDABLE SUPPORTIVE BRANCHED ENDOLUMINAL GRAFTS, Application Number 863,964, filed May 27, 1997, which matured into U.S. Patent No. 5,855,598;

WHEREAS, the **ASSIGNEE**, Corvita Corporation, 8210 N.W. 28th 27th Street, Miami, FL 33122 a corporation organized and existing under and by virtue of the laws of the State of Florida is desirous of acquiring the entire interest in and to said invention and the Letters Patent issued therefor;

KP 8/18/00
8/18/00
RA 8/18/00

NOW, THEREFORE, in consideration of One Dollar ($1.00) and of other good and valuable consideration, the receipt of which is hereby acknowledged, the undersigned, intending to be legally bound, does hereby sell, assign and transfer to the **ASSIGNEE** the **ASSIGNOR'S** entire right, title and interest, for the United States of America, its territories and possessions, and for all foreign countries, in said invention, including said letters patent all divisions and continuations thereof, all rights to claim priority based thereon, all rights to file foreign applications on said invention, and all reissues thereof, issuing for said invention in the United States of America and in any and all foreign countries.

It is agreed that **ASSIGNOR** shall be legally bound, upon request and at the expense of the **ASSIGNEE** or its successors or assigns or a legal representative thereof, to supply all information and evidence of which the undersigned has knowledge or possession, relating to the making and practice of said invention, to testify in any legal proceeding relating thereto, to execute all instruments and do such other acts as may be necessary and proper to patent the invention in the United States of America and foreign countries in the name of the **ASSIGNEE** and to execute all instruments proper to carry out the intent of this instrument.

ASSIGNOR hereby warrants that no assignment, sale, agreement or encumbrance has been or will be made or entered into which would conflict with this Assignment.

IN WITNESS WHEREOF, this Assignment is executed on the day indicated below.

ASSIGNOR: Typed Name: Rylser Alcime

Signature

Date: 8/18/2000

Witness as to ASSIGNOR: (Optional)

ASSIGNOR: Typed Name: Yasushi Kato

Signature

Date: Aug 18, 2000

Witness as to ASSIGNOR: (Optional)

PTO/SB/08A (AW 4/25/03) (04-03)
Approved for use through 04/30/2004. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE E
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Substitute for Form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

SHEET 1 of 4

Complete if Known	
Application Number	09/657,041
Filing Date	09/05/2000
First Named Inventor	Leonard Pinchuk et al.
Art Unit	3731
Examiner Name	Michael H. Thaler
Attorney Docket No.	BSI-430US8

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number: Number - Kind Code[2] (if known)	Publication Date (MM-DD-YYYY)	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-4,173,689	11/1979	Lyman et al.	entire document
		US-4,323,525	04/1985	Bornat	entire document
		US-4,459,252	07/1984	MacGregor	entire document
		US-4,475,972	10/1984	Wong	entire document
		US-4,512,338	04/1985	Balko et al.	entire document
		US-4,655,771	04/1987	Wallsten	entire document
		US-4,712,553	12/1987	MacGregor	entire document
		US-4,733,665	03/1988	Palmaz	entire document
		US-4,738,740	04/1988	Pinchuk et al.	entire document
		US-4,800,882	01/1989	Gianturco	entire document
		US-4,994,071	02/1991	MacGregor	entire document
		US-5,360,443	11/1994	Barone et al.	entire document
		US-5,385,580	01/1995	Schmitt	entire document
		US-4,604,762	08/1986	Robinson	entire document
		US-4,820,298	04/1989	Leveen et al.	entire document
		US-5,562,724	10/1996	Vorwerk	entire document
		US-5,653,747	08/1997	Dereume	entire document
		US-5,632,772	05/1997	Alcime et al.	entire document
		US-5,639,278	07/1997	Dereume et al.	entire document
		US-5,019,090	05/1991	Pinchuk	entire document

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document: Country Code[3] - Number[4] - Kind Code[5] (If known)	Publication Date (MM-DD-YYYY)	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
		EP 009941	04/1980			☐
		EP 461791	12/1991			☐
		DE 3918736	12/1990			☐
		GB 1205743	09/1970			☐
		GB 2115776	09/1983			☐
		WO 9206734	04/1992			☐

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

[1]Applicant's unique citation designation number (optional).

[2]See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04.

[3]Enter Office that issued the document, by the two-letter code (WIPO Standard St.3).

[4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

[5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible.

[6]Applicant is to place a check mark here if English language translation is attached.

PTO/SB/08A (AW 4/25/03) (04-03)
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Art Unit	3731
Examiner Name	Michael H. Thaler
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		US-5,156,620	10/1992	Pigott	entire document
		US-5,171,262	12/1992	MacGregor	entire document
		US-5,195,984	03/1993	Schatz	entire document
		US-5,104,399	04/1992	Lazarus	entire document
		US-5,116,360	05/1992	Pinchuk et al.	entire document
		US-5,236,447	08/1993	Kubo et al.	entire document
		US-5,290,305	03/1994	Inoue	entire document
		US-5,330,500	07/1994	Song	entire document
		US-5,354,308	10/1994	Simon et al.	entire document
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		US-4,950,227	08/1990	Savin et al.	entire document
		US-4,954,126	09/1990	Wallsten	entire document
		US-5,282,823	02/1994	Schwartz et al.	entire document
		US-5,443,499	08/1995	Schmitt	entire document
		US-3,700,380	10/1972	Kitrilakis	entire document

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		WO 92067334	04/1992			☐
		EP 539237	04/1993			☐
		WO 09246	06/1992			☐
		GB 2189150	10/1987			☐
		PCT 9513033	05/1995			☐
		PCT 9401056	01/1994			☐

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SHEET 3 of 4

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		US-4,286,341	09/1981	Greer et al.	entire document
		US-4,140,126	02/1979	Choudhury	entire document
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		US-4,739,762	04/1988	Palmaz	entire document
		US-4,776,337	10/1988	Palmaz	entire document
		US-5,092,877	03/1992	Pinchuk	entire document
		US-5,229,431	07/1993	Pinchuk	entire document
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		US-5,219,355	06/1993	Parodi et al.	entire document
		US-5,061,275	10/1991	Wallsten et al.	entire document
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		EP 551179	07/1993			☐
		EP 603959	09/1996			☐
		EP 686379	12/1995			☐
		WO 9413224	06/1994			☐
						☐
						☐

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PTO/SB/08B (AW 4/25/03) (04-03)
Approved for use through 04/30/2004. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for Form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

SHEET 4 of 4

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Filing Date	09/05/2000
First Named Inventor	Leonard Pinchuck et al.
Art Unit	3731
Examiner Name	Michael H. Thaler
Attorney Docket No.	BSI-430US8

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]
		"An Elastomeric Vascular Prosthesis", Trans. Am. Soc. Artif. Intern. Organs, Vol. XXIV, pages 209-214 (1978)	☐
		"Transfemoral Placement of Intraluminal Polyurethane Prosthesis for Abdominal Aortic Aneurysm", Journal of Surgical Research, 40, 305-309, 1986	☐
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[1]Applicant's unique citation designation number (optional).

[2]Applicant is to place a check mark here if English language translation is attached.

DOCKETED

PATENT
Case 807P028

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

U.S. Patent No. 5,855,598)
)
Issued: January 5, 1999)
)
Leonard Pinchuk)
)
EXPANDABLE SUPPORTIVE BRANCHED)
ENDOLUMINAL GRAFTS)

REQUEST FOR ISSUANCE OF
A CERTIFICATE OF CORRECTION
PURSUANT TO RULE 323

Assistant Commissioner for Patents
Washington, D.C. 20231

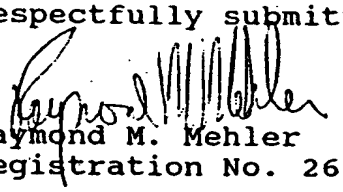
Sir:

The undersigned attorney respectfully requests issuance of a Certificate of Correction to correct typographical errors of minor character. Accompanying the present request is a form PTO 1050 showing these requested changes.

The changes being requested are clearly ones which have occurred in good faith and correction thereof is believed to be in strict compliance with the purpose, scope and intent of Rule 323 of Practice in Patent Cases and 35 U.S.C. § 255.

A check payable to the order of the Commissioner of Patents and Trademarks in the amount of $100.00 covering the statutory fee for issuance of this requested certificate is enclosed. Favorable consideration and approval of this request is respectfully requested.

Respectfully submitted,



Raymond M. Mehler
Registration No. 26,306

LOCKWOOD, ALEX
Three First National Plaza, Suite 1700
Chicago, Illinois 60602
(312) 782-4860

Dated: June 25, 1999

Staple Fee Only !

PRINTER'S TRIM LINE

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 5,855,598

DATED : January 5, 1999

INVENTOR(S) : Leonard Pinchuk

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the Cover Page, under "Attorney, Agent, or Firm", "Fitz-Gibbon" should read --FitzGibbon--.
Col. 4, line 56, "illustrated in of" should read --illustrated in--.
Col. 11, line 14, "means an" should read --means of an--.
Col. 13, line 45, "damages branched" should read --damages to branched--.
Col. 14, line 51, "liner, 122c" should read --liner 122c--.
Col. 16, line 40, "with invention" should read --with the invention--.

MAILING ADDRESS OF SENDER: Raymond M. Mehler, Esq.
LOCKWOOD, ALEX, FITZGIBBON & CUMMINGS
Three First National Plaza Suite 1700
Chicago, Illinois 60602

PATENT NO. 5,855,598

No. of add'l copies @ 50¢ per page

FORM PTO 1050 (Rev. 2-93)

These and other objects, features and advantages of this invention will be clearly understood through a consideration of the following detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be further elucidated in the following description with reference to the drawings, in which:

FIG. 1 is a perspective view, partially cut away, of an expandable supportive endoluminal graft construction in accordance with the invention;

FIG. 2 is a cross-sectional view along the line 2—2 of FIG. 1;

FIG. 3 is a perspective view, partially cut away, of another embodiment of the expandable supportive endoluminal graft construction;

FIG. 4 is a cross-sectional view along the line 4—4 of FIG. 3;

FIG. 5 is a perspective view, partially cut away, of a further embodiment of the expandable luminal graft construction;

FIG. 6 is a cross-sectional view along the line 6—6 of FIG. 5;

FIG. 7 is a perspective view, partially cut away, of a bifurcated expandable supportive endoluminal graft construction;

FIG. 8 is a cross-sectional view along the line 8—8 of FIG. 7;

FIG. 9 is a somewhat schematic view illustrating an early step in the implantation of a device such as shown in FIG. 7;

FIGS. 10, 11 and 12 are generally schematic views along the lines of FIG. 9 showing expansion of the main body and the branches of this bifurcated device;

FIG. 13 shows this bifurcated supportive graft after completion of the expansion procedure;

FIG. 14 illustrates another embodiment of a bifurcated expandable supportive endoluminal graft construction;

FIGS. 15, 16 and 17 illustrate implantation and assembly of the graft of FIG. 14;

FIGS. 18, 19, 20 and 21 illustrate a component branched graft and various stages of its separate, component deployment within a body vessel to repair an aneurysm, FIGS. 18 and 19 showing deployment of a preferred branched, longitudinally indented trunk component, and FIGS. 20 and 21 showing separate deployment of two branch components within the trunk component;

FIG. 22 is a top plan view of an embodiment of a branching trunk component in accordance with the invention;

FIG. 23 is a cross-sectional view along the line 23—23 of FIG. 22;

FIG. 24 is a side elevational view of the branching trunk component as illustrated in FIGS. 22 and 23;

FIG. 25 is an end view of the structure as shown in FIG. 24;

FIG. 26 is a perspective, generally exploded view of an example of a fixture suitable for forming the longitudinal crease in this trunk component;

FIG. 27 is a longitudinal broken-away view of the fixture of FIG. 26 with a braided cylindrical tube positioned therein;

FIG. 28 is a view generally in accordance with FIG. 27, showing formation of opposing crease indents in the braided cylindrical tube during formation of this trunk component;

components are illustrated in FIG. 18 through FIG. 21, which also illustrate their separate deployment with respect to each other within an aortic trunk. Same is shown in connection with treating an aneurysm such as an abdominal aorto-iliac aneurysm. The device includes a trunk component 101 which, in the illustrated use, is designed to extend from below the renal arteries to a location between the proximal neck of the aneurysm and the aorto-iliac bifurcation. It will be understood that this trunk component could also be shorter so that it terminates just below the proximal neck of the aneurysm, for example of a length which terminates within the dent or crease 124. In addition, the component bifurcated expandable supportive graft of this embodiment is self-expanding and is deployed by means of an introducer containing compressed expandable supportive graft components.

More particularly, and with reference firstly to FIG. 18, a guidewire 102 is first inserted in accordance with known procedures so as to traverse the aneurysm 103. Next, an introducer, generally designed as 104 having the trunk component therewithin in a radially compressed state is inserted over the guidewire 102. The introducer is maneuvered such that it is properly positioned as desired, in this case at a location distal of the distal end of the aneurysm. Then, the sheath 105 of the introducer is withdrawn, such as by sliding it in a proximal direction while the remainder of the introducer 104 remains in place. As the sheath is withdrawn, the trunk 101 expands, eventually achieving the deployed or implanted position shown in FIG. 19. At this stage, the distal portion 106 of the trunk is well anchored into the blood vessel wall and is suitably deployed.

FIG. 20 shows an introducer, generally designated as 107, having an independent tubular expandable supportive graft leg component 108 (FIG. 21) radially compressed therewithin. In this illustrated embodiment, this leg component is an iliac component of the bifurcated supportive graft being assembled within the body vessel. The introducer 107 is advanced until this iliac component is moved into a leg 109 of the already deployed trunk component 101. This positioning is illustrated in FIG. 21. It will be noted that the iliac tubular supportive graft component 108 extends from well within the leg 109 to a location proximal of the aneurysm in the iliac artery 110.

In a previous step, a guidewire had been passed through the appropriate vessel to iliac artery 112 until it crossed the aneurysm 103, while passing through the other leg 113 of the deployed trunk component 101. When the introducer for the previously radially compressed iliac component 115 had been removed, the component 115 had expanded radially and was deployed. Thus, the entirety of the bifurcated endoprosthesis or expandable supportive graft in accordance with this embodiment is fully deployed and assembled together as shown in FIG. 21, as well as generally depicted in FIGS. 29 and 30.

It will be noted that it is not required to actually attach the trunk component 101 and the tubular components 108, 115 together. In other words, these components are generally telescopically positioned with respect to each other. This telescopic feature allows some slippage between the trunk component and the tubular leg components, thereby providing a telescopic joint which functions as a slip bearing. It will be appreciated that it is generally desirable to firmly anchor portions of the bifurcated endoprosthesis within healthy vessel wall tissue. This can be achieved by the hoop strength of the supportive graft or by taking measures to enhance hoop strength at its ends, or by providing grasping structures such as hooks, barbs, flared ends and the like.

leg portions 109c and 113c are not so bonded to the stent portion 121c. This facilitates formation of the leg portions, which are typically pinched along the length of the legs in order to form at least one internal seam 126c. Leg openings 127c and 128c are thereby generally defined between this seam 126c and the adhesion zones 124c and 125c.

In FIG. 33, means are included in the trunk component 101*d* which provides enhanced securement upon implantation. A stent component 129*d* is included which has a substantially higher pitch angle (for example, between about 140° and 180°) than does the stent portion 121*d* therebelow within which the legs are positioned (for example, at a pitch angle of between about 70° and 90°). This higher pitch angle zone imparts a greater hoop strength upon deployment than does the stent 121c of the trunk component 101c. A barb 130 is also shown in order to further assist in securement of the endoprosthesis to the artery wall. When desired, the barb-type of structure can be a backing ring and barb formed out of the stent strand during its formation into the cylindrical supportive member.

Any of the various expandable supportive endoluminal graft, or stent graft, constructions discussed or referred to herein can be used in order to construct devices in accordance with this embodiment. Other modifications may also be incorporated, including tubes having stepped diameters or conical ends. The stent component can be made with flat wires or with pairs of wires or multifilament wires. They can incorporate balloon expandable stents, self-expanding stents, and combinations of balloon expandable stents and self-expanding stents. Use can be made of ancillary equipment such as endoluminal stapling devices or suturing devices in order to facilitate securement at the aneurysm neck, for example. Also, a portion of the stent component without a liner component or the like thereon can project at the proximal end of the endoluminal component, such as at a location which would be above the renal arteries. The objective is also to help to secure the device in place.

The prosthesis as discussed is deployed to replace or repair tubular bodies such as blood vessels, tracheas, ureters and the like, accommodating more than one conduit in order to divert flow to other branches of the tubular body. This allows for repair of a bifurcated area which is difficult to repair using a single-lumen device or a plurality of individual single-lumen devices. It is suitable for repair of damages branched conduits or, conversely, to repair conduits which converge into a single branch.

A preferred use for the bifurcating endoluminal grafts discussed herein is for insertion into a branching blood vessel. Same is typically suitable for use in the coronary vasculature (the right, left common, left anterior descending, and circumflex coronary arteries and their branches) and the peripheral vasculature (branches of the carotid, aorta, femoral, popliteal arteries and the like). These bifurcated devices are also suitable for implantation into other branching vessels such as in the gastrointestinal system, the tracheobronchial tree, the biliary system, and the genitourinary system.

It will be appreciated that the expandable supportive grafts in accordance with the present invention will dilate and/or support blood vessel lesions and other defects or diseased areas, including at or in proximity to sites of vascular bifurcations, branches and/or anastomoses. The expandable supportive graft is an integral structure that incorporates the expandable support component into the wall or walls of the elastomeric graft. Covers and/or linings that make up the grafts interface with body components that

facilitate normal cellular invasion without stenosis or recurrent stenosis when the graft is in its expanded, supportive orientation. The graft material is inert and biocompatible. The expandable supportive graft can be expanded from a smaller diameter insertion configuration to a larger diameter implantation configuration by the application of radially outwardly directed forces provided by expanding the endoprosthesis with a balloon catheter, using an ejection tube that allows a spring-into-place structure to be deployed from the end of a catheter into its expanded configuration, or by using a support component made of certain alloys exhibiting thermotransition characteristics by which they expand when heated, for example.

In addition to the support component structures illustrated herein, support structures include others having spring characteristics and those having a coil with circumferentially oriented fingers such as shown in Gianturco U.S. Pat. No. 4,800,882, incorporated by reference hereinto. U.S. Pat. Nos. 5,061,275, 5,219,355 and 5,336,500 relate to expanding or self-expanding endoluminal devices. Typically, these devices center on the use of a metallic structure imparting expansion attributes. U.S. Pat. Nos. 4,994,071 and 5,360,443 describe bifurcated devices which use expandable metallic stent structures and textile materials allowing branching of fluid flow. In general, materials of these patents, incorporated by reference hereinto, can be utilized in constructing components of the present invention.

More specifically, the tubular supportive component preferably is a braided tubular stent body made of metal alloy or any other material that is flexible, while being rigid and resilient when thus braided. Spring-type metals are typically preferred, such as stainless steel, titanium, stainless steel alloys, cobalt-chromium alloys, including alloys such as Elgiloy, Phynox and Conichrome. Thermal transition or memory function alloys such as nickel-titanium alloys including Nitinol are also suitable. Malleable metals including tantalum would be especially suitable for a structure that is not self-expanding.

Concerning the materials for the liner(s), they are typically polymeric materials in the form of a membrane or textile-like material, the objective being to reduce the porosity of the stent for proper tissue ingrowth and fluid tightness. Exemplary polymeric materials include polyesters such as polyethylene terephthalate, polyolefins such as polypropylene, or elastomeric materials such as polyurethane or silicone rubber. Combinations of these materials are also possible. In an especially preferred arrangement, the exterior liner which engages the tubular supportive component 121, when provided, is made of a double tricot polyester mesh knit, typically a Dacron type of material, while the interior liner 122*c* is made of a polyurethane. In an especially preferred arrangement, a thin coating or cover of polymer is provided over the braided wires of the tubular supportive component.

With further reference to the material out of which the cover and/or liner of the grafts in accordance with the present invention are made, the material must be stretchable with respect to the support component so that it will follow the movement of the endoprosthesis between its fully collapsed and expanded or implanted configurations. Polyurethanes are preferred. Particularly preferred is an especially crack-resistant, elastomeric and pliable polycarbonate urethane as described in Pinchuk U.S. Pat. Nos. 5,133,742 and 5,229,431, incorporated by reference hereinto.

In addition, various surface treatments can be applied to render the surfaces of the expandable supported graft more

identical as shown in FIG. 26. A larger sized mandrel cylinder will result in the formation of a larger trunk component leg 109, 113. This would typically also include shifting the location of the slits 135 so that the plane of blade insertion will line up with the troughs. It will be appreciated that the trifurcated arrangement is achieved by a three-component mandrel and three slits and blades that are 120° apart. Similarly, a four-branched structure would include four of each features, spaced 90° apart.

In a preferred arrangement for this embodiment, the thus deformed braided tubular supportive component is chemically and heat processed in order to set the desired diameter and mechanical properties of the main body. Once this flexible metallic stent with conformed shape is thus prepared, it is preferably lined as discussed elsewhere herein. It will be noted that the illustrated tubular braided mesh has a main cross-sectional area and has an outward flair at both ends. The braided structure is advantageously accommodated by the serrated structure of the blade edges 138, 139 in that the wire elements of the braid are grasped and secured at the ends of the bifurcation.

The expandable supportive graft of the present invention is capable of being tailored to meet specific needs, depending upon the particular defect or disease being addressed, such as occlusion, stenosis, aneurysm, arteriovenosis fistula, trauma and the like, as well as upon the anatomy of the vessel. For example, it can be desirable to have the support component of the expandable supportive graft at locations other than throughout the entirety of the graft as specifically illustrated in FIGS. 1 through 4 hereof. The bifurcated graft of FIGS. 7 and 8 shows some separation along the support component, such as between the trunk 61 and the branches 62, 63. It is also possible, with the grafts in accordance with the present invention, to provide an expandable graft having its supportive property emanating from one or more support components, while thereby providing an adjoining graft cylindrical portion which is supported primarily by its close proximity to a support component which can be presented at one end, both ends, or spaced along the expandable supportive graft in accordance with invention.

Such a structure is generally illustrated in FIG. 5, wherein an adjoining graft cylindrical portion 71 is positioned between a first support component 72 and another or second support component 73. The expandable supportive graft in accordance with the present invention provides the tailorability advantage of being able to vary within a single graft the configuration, structure and properties of the support component or components of the graft. These various properties allow the expandable supportive graft to be tailored in accordance with particular needs of the disease, defect or damage being treated. For example, support may be particularly desirable at one location being treated, while a less rigid supportive area is needed at another, generally adjoining location. By the expandable supportive graft in accordance with this invention, a single graft can be deployed in order to effect two or more different functions. By achieving multiple support and/or repair functions with a single device, possible trauma to the patient is minimized by reducing the number of transluminal passages needed to address a situation that could otherwise require separate stents or grafts, each of which is separately deployed or implanted.

With further reference to the tailorability aspects, the present invention reduces the risk of compromising the patency of the passageways being treated. This is particularly true in treating lesions at or near vascular bifurcations, branches and/or anastomoses. Typical difficulties which can

SUPPLEMENTAL REISSUE APPLICATION DECLARATION BY THE INVENTOR

Docket Number (Optional)
BSI-430US8

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is described and claimed in patent number 5,855,598 granted January 5, 1999, and for which a reissue patent is sought on the invention entitled EXPANDABLE SUPPORTIVE BRANCHED ENDOLUMINAL GRAFTS,

the specification of which

☐ is attached hereto.

☒ was filed on September 5, 2000 as reissue application number 09/657,041 and was amended on _____.
(If applicable)

I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.

I verily believe the original patent to be wholly or partly inoperative or invalid, for the reasons described below. (Check all boxes that apply.)

☐ by reason of a defective specification or drawing.

☒ by reason of the patentee claiming less than he had the right to claim in the patent.

☐ by reason of other errors.

At least one error upon which reissue is based is described below. If the reissue is a broadening reissue, such must be stated with an explanation as to the nature of the broadening:

This reissue is a broadening reissue. At least the following errors exist as a basis for this reissue:

1. Originally the claims required that the liner of the trunk component have both a generally cylindrical upper body portion and a generally cylindrical lower body portion. The error is that this is unduly narrow in that the liner need only have a generally cylindrical body portion and two leg portions.

2. Originally the claims required several steps to make a supportive graft, including inserting and inflating a liner. The error here is that this is unduly narrow in that the specification also teaches simply a method of forming a supporting component comprising the steps of forming a support component and crimping at least one portion to provide a multiple-lumen portion.

(REISSUE APPLICATION DECLARATION BY THE INVENTOR, page 2)

Docket Number (Optional)
BSI-430US8

All errors corrected in this reissue application arose without any deceptive intention on the part of the applicant. As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

Name(s)	Registration Number
Jonathan H. Spadt	45,122
Paul F. Prestia	23,031
(additional listed on attached sheet)	

Correspondence Address: Direct all communications about the application to:

☒ Customer Number 23122 → Place Customer Number Bar Code Label here

OR *Type Customer Number here*

☐ Firm or Individual Name					
Address					
Address					
City		State		ZIP	
Country					
Telephone		Fax			

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine and imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this declaration is directed.

Full name of sole or first inventor (given name, family name)
Leonard Pinchuk

Inventor's signature

Residence Miami, Florida	Date
Mailing Address 13704 SW 92 Court Miami, Florida 33176	Citizenship USA

Full name of second joint inventor (given name, family name)
Rysler Alcime

Inventor's signature	Date
Residence Miami, Florida	Citizenship USA

Mailing Address 925 N.E. 122th Street
Miami, Florida 33161

Full name of third joint inventor (given name, family name)
Yasushi Kato

Inventor's signature	Date
Residence Pembroke Pines, Florida 33029	Citizenship USA

Mailing Address
311 S.W. 187th Avenue
Pembroke Pines, Florida 33029

☐ Additional joint inventors are named on separately numbered sheets attached hereto.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No:	09/657,041
Applicant:	Leonard Pinchuk et al.
Filed:	9/5/2000
Title:	Expandable Supportive Branched Endoluminal Grafts
T.C./A.U.:	3731
Examiner:	Michael H. Thaler
Confirmation No.:	9622
Docket No.:	BSI-430US8

COMMUNICATION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with telephone conversations between the applicants' below signed representative and Examiner Thaler on October 24, 2003 and December 8, 2003, the applicants respectfully submit the following to satisfy remaining formality requirements:

1. **Supplemental Reissue Oath/Declaration**

A Supplemental Reissue Oath/Declaration is submitted herewith to further identify the at least one error which is relied upon to support the reissue application. This Declaration has been executed by two of the three inventors, namely Leonard Pinchuk and Yasushi Kato. The remaining inventor, Rysler Alcime, is in the process of returning to the country to sign the Declaration. The fully executed Supplemental Reissue Oath/Declaration will be submitted shortly upon execution by Rysler Alcime.

2. **Replacement Drawing Sheet**

Also enclosed is the drawing sheet containing Figures 14-17 with "Replacement Sheet" marked thereon indicating that changes were made to the drawings.

3. **Claims**

A copy of claims 40-42 which were previously submitted are now enclosed with all of the claims being underlined.

4. **Patent**

The original U.S. Patent No. 5,855,598 issued January 5, 1999 is enclosed for surrender.

Conclusion

The applicants respectfully assert that all requirements by the Examiner have now been met (with the exception of the fully Executed Supplemental Oath/Declaration which will be submitted forthwith). A notice of allowance of a Reissue Patent with claims 1-30 and 40-42 is respectfully requested upon submission of the Executed Supplemental Oath/Declaration.

Respectfully submitted,

Jonathan H. Spadt, Reg. No. 45,122
Attorney for Applicants

JHS/dhm

Attachments: Replacement Sheet of Figures 14-17 (1 sheet)
Partially executed Supplemental Reissue Oath/Declaration
Claims 40-42 (underlined)
Original U.S. Patent No. 5,855,598

Dated: December 9, 2003

☒ P.O. Box 980
Valley Forge, PA 19482
(610) 407-0700

☐ P.O. Box 1596
Wilmington, DE 19899
(302) 778-2600

The Commissioner for Patents is hereby authorized to charge payment to Deposit Account No. **18-0350** of any fees associated with this communication.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, with sufficient postage, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on:

December 9, 2003

Denise Moya

40. A multi-component bifurcating expandable supportive endoluminal graft comprising:

a plurality of expandable supportive endoluminal components adapted to be individually deployed at a selected location within a body vessel, each said supportive endoluminal graft component being radially compressible for endoluminal insertion and radially expandable for deployment at a desired location within a body vessel;

one of said expandable supportive endoluminal components is a trunk component, said trunk component generally surrounding a trunk liner positioned within said trunk component, said trunk liner having a generally cylindrical body portion and two leg portions, each said leg portion defining a leg opening, wherein the generally cylindrical body portion of said liner and portions of said leg portions abut said tubular supporting member and are secured to said tubular supporting member, and portions of said leg portions not abutting said tubular supporting member abut one another and are secured to one another;

at least one other of said expandable supportive endoluminal components is a generally cylindrical supportive leg component; and

said generally cylindrical supportive leg component and one of said leg portions of said liner, when said leg component and trunk component are deployed within the body vessel, are telescopically positioned with respect to each other.

41. The supportive endoluminal graft of claim 40, wherein said generally cylindrical supportive leg component has an end portion which, when deployed, is positioned within said leg opening of the trunk liner.

42. The supportive endoluminal graft of claim 40 or claim 41, wherein said plurality of expandable supportive endoluminal components are self-expanding.

FIG.14

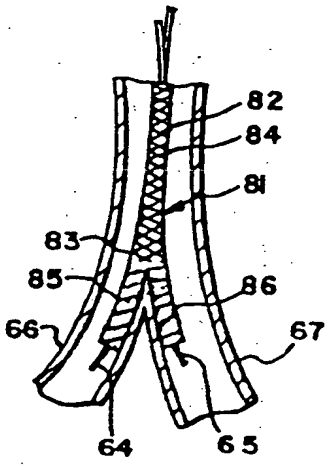


FIG.15

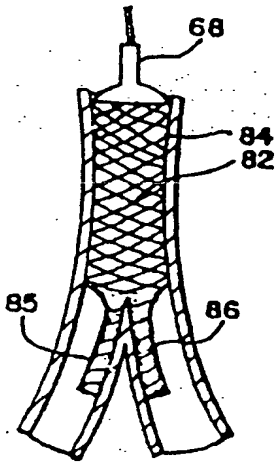


FIG.16

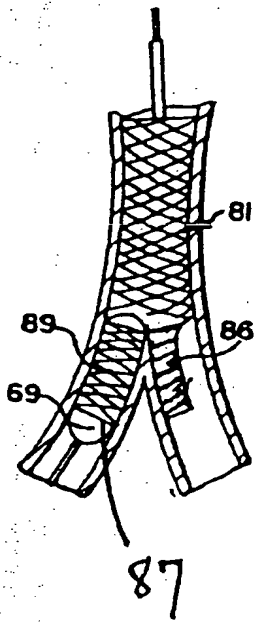
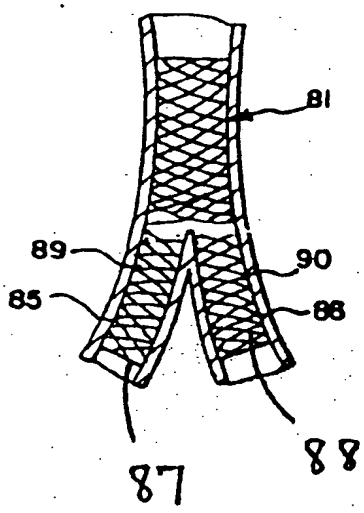


FIG.17



PTO/SB/51 (10-00)
Approved . . use through 10/31/2002. OMB 0651-0033
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

SUPPLEMENTAL REISSUE APPLICATION DECLARATION BY THE INVENTOR

Docket Number (Optional)
BSI-430US8

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is described and claimed in patent number 5,855,598 granted January 5, 1999 , and for which a reissue patent is sought on the invention entitled EXPANDABLE SUPPORTIVE BRANCHED ENDOLUMINAL GRAFTS,

the specification of which

☐ is attached hereto.

☒ was filed on September 5, 2000 as reissue application number 09/657,041
and was amended on _____ .
(If applicable)

I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.

I verily believe the original patent to be wholly or partly inoperative or invalid, for the reasons described below. (Check all boxes that apply.)

☐ by reason of a defective specification or drawing.

☒ by reason of the patentee claiming less than he had the right to claim in the patent.

☐ by reason of other errors.

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(REISSUE APPLICATION DECLARATION BY THE INVENTOR, page 2)

Docket Number (Optional)
BSI-430US8

All errors corrected in this reissue application arose without any deceptive intention on the part of the applicant. As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

Name(s)	Registration Number
Jonathan H. Spadt	45,122
Paul F. Prestia	23,031
(additional listed on attached sheet)	

Correspondence Address: Direct all communications about the application to:

☒ Customer Number 23122 → Place Customer Number Bar Code Label here

OR *Type Customer Number here*

☐ Firm or Individual Name					
Address					
Address					
City		State		ZIP	
Country					
Telephone		Fax			

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine and imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this declaration is directed.

Full name of sole or first inventor (given name, family name)
Leonard Pinchuk

Inventor's signature Leonard Pinchuk

Residence
Miami, Florida

Date
October 2, 2003

Mailing Address
13704 SW 92 Court
Miami, Florida 33176

Citizenship
USA

Full name of second joint inventor (given name, family name)
Rysler Alcime

Inventor's signature

Date

Residence
Miami, Florida

Citizenship
USA

Mailing Address 925 N.E. 122th Street
Miami, Florida 33161

Full name of third joint inventor (given name, family name)
Yasushi Kato

Inventor's signature Yasushi Kato

Date
Oct. 02, 2003

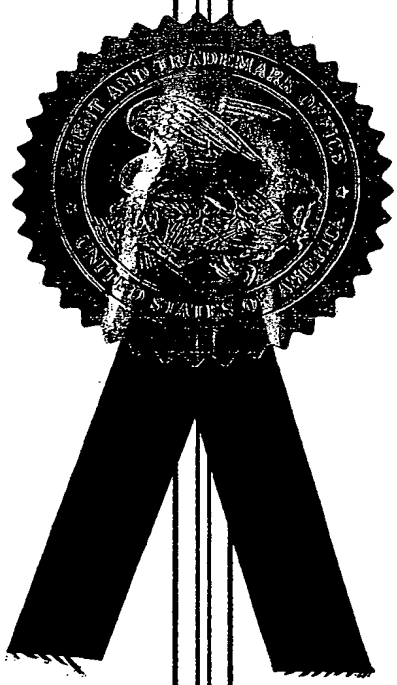
Residence
Pembroke Pines, Florida 33029

Citizenship
~~USA~~ JAPAN YK 10/2/03

Mailing Address
311 S.W. 187th Avenue
Pembroke Pines, Florida 33029

☐ Additional joint inventors are named on separately numbered sheets attached hereto.

The United States of America



The Commissioner of Patents and Trademarks

Has received an application for a patent for a new and useful invention. The title and description of the invention are enclosed. The requirements of law have been complied with, and it has been determined that a patent on the invention shall be granted under the law.

Therefore, this

United States Patent

Grants to the person(s) having title to this patent the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States of America or importing the invention into the United States of America for the term set forth below, subject to the payment of maintenance fees as provided by law.

If this application was filed prior to June 8, 1995, the term of this patent is the longer of seventeen years from the date of grant of this patent or twenty years from the earliest effective U.S. filing date of the application, subject to any statutory extension.

If this application was filed on or after June 8, 1995, the term of this patent is twenty years from the U.S. filing date, subject to any statutory extension. If the application contains a specific reference to an earlier filed application or applications under 35 U.S.C. 120, 121 or 365(c), the term of the patent is twenty years from the date on which the earliest application was filed, subject to any statutory extension.

Acting Commissioner of Patents and Trademarks

Attest

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No:	09/657,041
Applicant:	Leonard Pinchuk et al.
Filed:	9/5/2000
Title:	Expandable Supportive Branched Endoluminal Grafts
TC/A.U.:	3731
Examiner:	Michael H. Thaler

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98 and to the duty of disclosure set forth in 37 C.F.R. § 1.56, the Examiner in charge of the above-identified application is requested to consider and make of record the references listed on the PTO 1449 (RP) submitted herewith. A copy of each of the listed references is also enclosed.

Although the information submitted herewith may be "material" to the Examiner's consideration of the subject application, this submission is not intended to constitute an admission that such information is "prior art" as to the claimed invention.

In accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

References Y are not in the English language, but this reference was cited by a foreign patent office in a counterpart foreign application. A copy of this English language search report, indicating the degree of relevance determined by the foreign patent office is submitted herewith. MPEP Section 609A(3), second paragraph.

More than three months have elapsed since the filing of the above-referenced application and/or a first (non-Final) Official Action has been received. No Final Action or Notice of Allowance has yet been received and it is presumed that none has yet been mailed. Accordingly, as more specifically indicated below, a statement as required by 37 C.F.R. § 1.97(c) is provided herewith.

STATEMENT

The undersigned hereby states that

☒ each item of information disclosed in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the Information Disclosure Statement.

☐ no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing this statement after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months before the filing of the Information Disclosure Statement.

Respectfully submitted,

Jonathan H. Spadt, Reg. No. 45,122
Attorney for Applicants

JHS/dhm

Enclosures: PTO Form 1449
(37) References
Office Action
Transmittal Form

Dated: February 9, 2004

☒ P.O. Box 980
Valley Forge, PA 19482
(610) 407-0700

☐ P.O. Box 1596
Wilmington, DE 19899
(302) 778-2500

The Commissioner for Patents is hereby authorized to charge payment to Deposit Account No. **18-0350** of any fees associated with this communication.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, with sufficient postage, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on:

February 9, 2004

Denise Moya

(AW 08/03)

Substitute for Form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

SHEET 1 of 3

Complete if Known	
Application Number	09/657,041
Filing Date	9/5/2000
First Named Inventor	Leonard Pinchuk et al.
Art Unit	3731
Examiner Name	Michael H. Thaler
Attorney Docket No.	BSI-430US8

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number: Number - Kind Code[2] (if known)	Publication Date (MM-DD-YYYY)	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-5,334,201	08/02/1994	Cowan	entire document
		US-5,019,393	05/28/1991	Ito et al.	entire document
		US-4,300,244	11/17/1981	Bokros	entire document
		US-4,879,135	11/7/1989	Greco et al.	entire document
		US-4,786,556	11/22/1988	Hu et al.	entire document
		US-3,526,005	09/01/1970	Bokros	entire document
		US-3,685,059	08/22/1972	Bokros et al	entire document
		US-4,544,599	10/01/1985	Buttazzoni	entire document
		US-4,878,906	11/7/1989	Lindemann et al.	entire document
		US-4,739,762	04/26/1988	Palmaz	entire dcoument
		US-4,768,507	09/06/1988	Fischell et al.	entire document
		US-5,213,580	05/25/1993	Slepian et al.	entire document
		US-5,464,450	11/7/1995	Buscemi et al.	entire document
		US-4,553,545	11/19/1985	Maass et al.	entire document
		US-4,836,884	06/06/1989	McAuslan	entire document
		US-5,181,903	01/26/1993	Vann et al.	entire document
		US-5,405,377	04/11/1995	Cragg	entire document
		US-5,263,992	11/23/1993	Guire	entire document
		US-4,562,596	01/07/1986	Kornberg	entire document
		US-5,387,235	02/07/1995	Chuter	entire document
		US-4,973,493	11/27/1990	Guire	entire document

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document: Country Code[3] - Number[4] - Kind Code[5] (If known)	Publication Date (MM-DD-YYYY)	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
		EP 0 645 125 A1	03/29/1995	Sooho Medi-Tech Co., Ltd.	entire document	☐
		WO 95/16406	06/22/1995	William Cook Europe	entire document	☐
		WO 94/16646	08/04/1994	Schneider Inc.	entire document	☐
		WO 83/03752	11/10/1983	Hans Wallsten	entire document	☐
		WO 95/21592	08/17/1995	Mintec, Inc.	entire document	☐
		WO 93/13825	07/22/1993	State of Oregon	entire document	☐

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

[1] Applicant's unique citation designation number (optional).

[2] See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04.

[3] Enter Office that issued the document, by the two-letter code (WIPO Standard St.3).

[4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

[5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible.

[6] Applicant is to place a check mark here if English language translation is attached.

PTO/SB/08a (08-03) (AW 10/2003)
Approved for use through 7/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for Form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

SHEET 2 of 3

Complete if Known	
Application Number	09/657,041
Filing Date	9/5/2000
First Named Inventor	Leonard Pinchuk et al.
Art Unit	3731
Examiner Name	Michael H. Thaler
Attorney Docket No.	BSI-430US8

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number: Number - Kind Code[2] (If known)	Publication Date (MM-DD-YYYY)	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-4,678,468	07/07/1987	Hiroyoshi	entire document
		US-			
		US-			
		US-			
		US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document: Country Code[3] - Number[4] - Kind Code[5] (If known)	Publication Date (MM-DD-YYYY)	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
		EP 0 328 421 A2	08/16/1989	Trustees of Columbia University in the City of New York	entire document	☐
		EP 0 335 341 A1	10/04/1989	Expandable Grafts Partnership	entire document	☐
		WO 89/05664	06/29/1989	Allied-Signal Inc.	entire document	☐
		Published Japanese Translation No. HEI 7-500272			entire document	☐
		Japanese Unexamined Patent Application, First Publication No. HEI 7-265438			entire document	☐
		Published Japanese Translation No. Sho 59-500652			entire document	☐
		Japanese Unexamined Patent Application, First Publication No. Sho 61-45765			entire document	
		Japanese Unexamined Patent Application, First Publication No. Sho 58-203181			entire document	
		Japanese Unexamined Patent Application, First Publication No. Sho 54-34493			entire document	
		Japanese Unexamined Patent Application, First Publication No. Hei 2-17071			entire document	
		Japanese Unexamined Patent Application, First Publication No. Hei 1-299550			entire document	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

[1] Applicant's unique citation designation number (optional).

[2] See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04.

[3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3).

[4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

[5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible.

[6] Applicant is to place a check mark here if English language translation is attached.

(AW 08/03)

Substitute for Form 1449B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

SHEET 3 of 3

Complete if Known	
Application Number	09/657,041
Filing Date	9/5/2000
First Named Inventor	Leonard Pinchuk et al.
Art Unit	3731
Examiner Name	Michael H. Thaler
Attorney Docket No.	BSI-430US8

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]
		Copy of Japanese Official Action for Application No. HEI 9-518880 dated 12/22/2003	☐
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No:	09/657,041
Applicant:	Leonard Pinchuk et al.
Filed:	9/5/2000
Title:	Expandable Supportive Branched Endoluminal Grafts
T.C./A.U.:	3731
Examiner:	Michael H. Thaler
Confirmation No.:	9622
Docket No.:	BSI-430US8

SUPPLEMENTAL AMENDMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Please amend the above-identified application as follows:

☒ **Amendments to the Claims** are reflected in the listing of claims which begins on page 2 of this paper.

☒ **Remarks/Arguments** begin on page 9 of this paper.

Amendments to the Claims: This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

1. (Original) A multiple-component branched expandable supportive endoluminal graft comprising:

a plurality of expandable supportive endoluminal components which are deployed individually at a selected location within a body vessel, each said supportive endoluminal graft component being radially compressible for endoluminal insertion and radially expandable for deployment at a desired location within a body vessel;

one of said expandable supportive endoluminal components is a trunk component, said trunk component including a tubular supporting member and a trunk liner positioned along said tubular supporting member, said trunk liner having a generally cylindrical upper body portion, at least two leg portions, and a generally cylindrical lower body portion, each said leg portion defining a leg opening into said upper body portion and another leg opening into said lower body portion;

at least one other of said expandable supportive endoluminal components is a generally cylindrical supportive leg component; and

said generally cylindrical supportive leg component and one of said leg portions of the trunk component, when said leg component and trunk component are deployed within the body vessel, are telescopically positioned with respect to each other.

2. (Original) The supportive endoluminal graft in accordance with claim 1, wherein said generally cylindrical supportive leg component has an end portion which, when deployed, is positioned within one said leg opening of the trunk component.

3. (Original) The supportive endoluminal graft in accordance with claim 1, wherein said plurality of expandable supportive endoluminal components are self-expanding.

4. (Original) The supportive endoluminal graft in accordance with claim 1, wherein said plurality of expandable supportive endoluminal components are deployed by a radially expandable device.

5. (Original) The supportive endoluminal graft in accordance with claim 1, wherein said generally cylindrical supportive component includes a generally cylindrical supporting member and a generally cylindrical liner secured therealong.

6. (Original) The supportive endoluminal graft in accordance with claim 1, wherein said trunk liner is a stretchable wall of essentially inert biocompatible material, said stretchable wall being attached to a portion of the internal surface of the trunk component tubular supporting member, said stretchable wall having a diameter size that expands with said trunk component tubular supporting member.

7. (Original) The supportive endoluminal graft in accordance with claim 5, wherein said liner of the generally cylindrical supportive leg component is a stretchable wall of essentially inert biocompatible material, said stretchable wall being applied onto at least the internal surface of

the generally cylindrical tubular supporting member of the leg component.

8. (Original) The supportive endoluminal graft in accordance with claim 1, wherein said at least two leg portions of the trunk liner are partially defined by a longitudinal seam which extends generally between said generally cylindrical upper and lower body portions of the trunk liner.

9. (Original) The supportive endoluminal graft in accordance with claim 8, wherein said leg portions are further defined by portions of the trunk liner which are secured to the tubular supporting member at a location spaced radially from said longitudinal seam.

10. (Original) The supportive endoluminal graft in accordance with claim 1, wherein said leg portions of the trunk liner are longitudinally generally coextensive with a central longitudinal portion of said tubular supporting member of the trunk component.

11. (Original) The supportive endoluminal graft in accordance with claim 10, wherein an outside section of each of said leg portions of the trunk liner is secured to said tubular supporting member, while inside sections of each of said leg portions are secured to each other along an internal seam.

12. (Original) The supportive endoluminal graft in accordance with claim 1, wherein said generally cylindrical supportive leg component, when deployed, is telescopically slidably positioned within one of said leg portions of the trunk component.

13. (Original) The supportive endoluminal graft in accordance with claim 5, wherein said liner of the leg component and said trunk liner are each a stretchable wall made from a porous elastomeric material that provides a structure which allows normal cellular invasion thereinto from the body vessel when implanted therewithin.

14. (Original) The supportive endoluminal graft in accordance with claim 13, wherein said porous elastomeric material of each stretchable wall is an elastomeric polymer.

15. (Original) The supportive endoluminal graft in accordance with claim 13, wherein said porous elastomeric material of said stretchable wall is a polycarbonate urethane.

16. (Original) The supportive endoluminal graft in accordance with claim 13, wherein said porous elastomeric material is coated with a thin layer of silicone rubber.

17. (Original) The supportive endoluminal graft in accordance with claim 5, wherein said trunk liner and said liner of the leg component are each a stretchable wall along the internal surface and the external surface of each tubular supporting component.

18. (Original) The supportive endoluminal graft in accordance with claim 1, wherein an exposed longitudinal end of said tubular supporting member extends longitudinally beyond and is not completely covered by said liner.

19. (Original) The supportive endoluminal graft in accordance with claim 1, wherein said tubular supporting component includes a plurality of wire strands with open areas therebetween.

20. (Original) The supportive endoluminal graft in accordance with claim 19, wherein said wire

strands of the tubular supporting component are generally sinusoidally configured wire that is helically wound into the tubular supporting component, said wire defining therebetween said open areas of the tubular supporting component.

21. (Original) The supportive endoluminal graft in accordance with claim 19, wherein said wire strands of the tubular supporting component are shaped as intersecting elongated lengths integral with each other and defining said openings therebetween to form a mesh-shaped tubular supporting component.

22. (Original) The supportive endoluminal graft in accordance with claim 1, wherein said trunk component includes a projecting securement member.

23. (Original) A multiple-component branching expandable supportive endoluminal graft comprising:

a plurality of expandable supportive endoluminal graft components which are deployed individually at a selected location within a body vessel, each said supportive endoluminal graft component being radially compressible and radially expansible;

one of said expandable supportive endoluminal graft components being a trunk component having a longitudinal axis, an internal liner including a seam disposed generally along the longitudinal axis, and an external surface which is generally cylindrical and spaced outwardly from said internal liner, said trunk component having a plurality of legs defined in part by said seam, said trunk component further having two generally cylindrical body portions which flank said seam and which extend in opposite directions from said legs;

at least one other of said expandable supportive endoluminal graft components being a generally cylindrical supportive leg component;

said trunk component liner being a stretchable wall of essentially inert biocompatible material, said stretchable wall being applied onto an internal surface of a tubular supporting component; and

each said leg is sized and shaped to receive said generally cylindrical supportive leg component.

24. (Original) The branching graft according to claim 23, wherein said trunk component has a network of land areas with open areas defined therebetween.

25. (Original) A method for making a multi-component bifurcating expandable supportive endoluminal graft, comprising the steps of:

providing a generally tubular self-supporting member;

providing a generally cylindrical liner made of flexible material, and flattening said liner so opposing surfaces engage each other;

forming a longitudinal seam within the thus flattened liner in order to secure opposing longitudinal portions of the liner to each other;

inserting the thus seamed liner within the generally tubular self-supporting member;

inflating the seamed liner while within the self-supporting member until radially extending surfaces of the liner engage an inner surface of the tubular self-support member; and

securing said liner radially extending surfaces onto the thus engaged inner surface of the tubular self-supporting member in order to thereby assemble a branched trunk component.

26. (Original) The method of claim 25 further including providing a further expandable supportive endoluminal graft component by providing a generally cylindrical supportive leg component which is sized to be telescopically assembled with one of the leg portions of the branched trunk component.

27. (Original) The method of claim 25, wherein said inflating step includes filling the seamed liner with elutable materials.

28. (Original) The method in accordance with claim 25, wherein said inflating step includes inserting an expandable elongated tool into the seamed liner and expanding same so as to dilate the seamed liner into engagement with the self-supporting member.

29. (Original) The method in accordance with claim 25, wherein said step of forming a longitudinal seam includes applying heat along the longitudinal seam location.

30. (Original) The method in accordance with claim 25, wherein said step of forming a longitudinal seam includes suturing.

31-39 (Cancel)

40. (Previously Presented) A multi-component bifurcating expandable supportive endoluminal graft comprising:

a plurality of expandable supportive endoluminal components adapted to be individually deployed at a selected location within a body vessel, each said supportive endoluminal graft component being radially compressible for endoluminal insertion and radially expandable for deployment at a desired location within a body vessel;

one of said expandable supportive endoluminal components is a trunk component, said trunk component generally surrounding a trunk liner positioned within said trunk component, said trunk liner having a generally cylindrical body portion and two leg portions, each said leg portion defining a leg opening, wherein the generally cylindrical body portion of said liner and portions of said leg portions abut said trunk component and are secured to said trunk component, and portions of said leg portions not abutting said trunk component abut one another and are secured to one another;

at least one other of said expandable supportive endoluminal components is a generally cylindrical supportive leg component; and

said generally cylindrical supportive leg component and one of said leg portions of said liner, when said leg component and trunk component are deployed within the body vessel, are telescopically positioned with respect to each other.

41. (Previously Presented) The supportive endoluminal graft of claim 40, wherein said generally cylindrical supportive leg component has an end portion which, when deployed, is positioned within said leg opening of the trunk liner.

42. (Previously Presented) The supportive endoluminal graft of claim 40 or claim 41, wherein said plurality of expandable supportive endoluminal components are self-expanding.

43. (New) An endoluminal support device comprising:

a radially-expandable, bifurcated support,

the support including:

a first support portion, and

a second support portion including a first lobe and a second lobe, and a longitudinal isthmus between the first lobe and the second lobe,

the first and second lobes having smaller diameters than the first portion; and

a liner coupled to the radially-expandable, bifurcated support,

wherein the endoluminal support device has an uninterrupted cross-section over its entire length.

44. (New) The endoluminal support device of claim 43, wherein the liner is coupled to an interior side of the radially-expandable, bifurcated support.

45. (New) The endoluminal support device of claim 43, wherein the liner is coupled to an exterior side of the radially-expandable, bifurcated support.

46. (New) The endoluminal support device of claim 43, wherein each of the first and second lobes is adapted to receive a branch support.

47. (New) A branching endovascular prosthesis comprising:

a radially expandable support, the support including:

a distal support portion comprising at least one expandable circumferential portion, and

a proximal support portion including a first lobe and a second lobe separated from the first lobe by an isthmus, and

a bifurcated liner coupled to the distal support portion and to the proximal support portion,

wherein the branching endovascular prosthesis has an uninterrupted cross-section over its entire length.

48. (New) The prosthesis of claim 47, wherein the bifurcated liner is coupled to an interior side of the distal support portion and to an interior side of the proximal support portion.

49. (New) The prosthesis of claim 47, wherein the bifurcated liner is coupled to an exterior side of the distal support portion and to an exterior side of the proximal support portion.

50. (New) The prosthesis of claim 47, wherein the prosthesis is self expanding.

51. (New) A branching endovascular prosthesis comprising:

a distal support portion comprising at least one radially expandable portion;

a proximal support portion coupled to the distal support portion,

the proximal support portion including a first radially expandable lobe and a second radially expandable lobe separated from the first lobe by an isthmus; and

a bifurcated liner coupled to the distal support portion and to the proximal support portion,

wherein the branching endovascular prosthesis has an uninterrupted cross-section over its entire length.

52. (New) The prosthesis of claim 51, wherein the bifurcated liner is coupled to an interior side of the distal support portion and to an interior side of the proximal support portion.

53. (New) The prosthesis of claim 51, wherein the bifurcated liner is coupled an exterior side of the distal support portion and to an exterior side of the proximal support portion.

54. (New) A branching endoluminal prosthesis comprising:

a liner and a radially expandable support coupled to said liner;

wherein said liner comprises:

a main body having a proximal portion and a distal portion, said proximal portion including a main lumen, and said distal portion including a first branch having a first lumen extending to a first distal end, and a second branch having a second lumen extending to a second distal end, the first and second branch lumens being in communication with the main lumen and extending through said distal portion to define a bifurcation extending to said first and second distal ends; and

wherein said support comprises:

a distal support portion disposed over said distal portion of said main body, said distal support portion comprising at least one expandable circumferential portion defining a first lobe supporting said first branch, a second lobe supporting said second branch, and opposed indentations to support and separate said first and second branches,

wherein said branching endoluminal prosthesis has an uninterrupted cross-section over its entire length.

55. (New) The branching endoluminal prosthesis of claim 54 wherein said support further comprises an expandable proximal circumferential portion supporting said proximal portion of said main body.

56. (New) The branching endoluminal prosthesis of claim 54 further comprising an attachment mechanism which couples said distal support to said distal portion of said main body of said liner.

57. (New) The branching endoluminal prosthesis of claim 56 wherein said attachment mechanism attaches said first lobe and a portion of each indentation to the first branch.

58. (New) The branching endoluminal prosthesis of claim 57 wherein said attachment mechanism attaches said second lobe and a portion of each indentation to the second branch.

Remarks

Applicants have filed this supplemental amendment to pursue the above claims, which are directed to exemplary features of a prosthesis. Newly added claims 43-58 are substantially copied from U.S. Patent No. 6,576,009 which issued to Ryan et al. on June 10, 2003. A copy of the Ryan patent is submitted herewith for the Examiner's convenience.

Respectfully submitted,

Jonathan H. Spadt, Reg. No. 45,122
Attorney for Applicants

JHS/dhm

Enclosure: Copy of U.S. Patent No. 6,576,009

Dated: June 8, 2004

☒ P.O. Box 980
Valley Forge, PA 19482
(610) 407-0700

☐ P.O. Box 1596
Wilmington, DE 19899
(302) 778-2600

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June 8, 2004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No:	09/657,041
Applicant:	Leonard Pinchuk et al.
Filed:	9/5/2000
Title:	Expandable Supportive Branched Endoluminal Grafts
TC/A.U.:	3731
Examiner:	Michael H. Thaler

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98 and to the duty of disclosure set forth in 37 C.F.R. § 1.56, the Examiner in charge of the above-identified application is requested to consider and make of record the references listed on the PTO 1449 (RP) submitted herewith. A copy of each of the listed references is also enclosed.

Although the information submitted herewith may be "material" to the Examiner's consideration of the subject application, this submission is not intended to constitute an admission that such information is "prior art" as to the claimed invention.

In accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

More than three months have elapsed since the filing of the above-referenced application and a first (non-Final) Official Action has been received. No Final Action or Notice of Allowance has yet been received and it is presumed that none has yet been mailed. Accordingly, as more specifically indicated below, a statement as required by 37 C.F.R. § 1.97(c) is provided herewith.

STATEMENT

The undersigned hereby states that

☒ each item of information disclosed in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the Information Disclosure Statement.

☐ no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing this statement after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months before the filing of the Information Disclosure Statement.

Respectfully submitted,

Jonathan H. Spadt, Reg. No. 45,122
Attorney for Applicants

JHS/dhm

Enclosures: PTO Form 1449
(4) References
Search Report
Transmittal Form

Dated: July 15, 2004

☒ P.O. Box 980
Valley Forge, PA 19482
(610) 407-0700

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July 15, 2004

Denise Moya

(AW 08/03)

Substitute for Form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

SHEET 1 of 2

Complete if Known	
Application Number	09/657,041
Filing Date	9/5/2000
First Named Inventor	Leonard Pinchuk et al.
Art Unit	3731
Examiner Name	Michael H. Thaler
Attorney Docket No.	BSI-430US8

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number: Number - Kind Code[2] (if known)	Publication Date (MM-DD-YYYY)	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-4,374,669	02/22/1983	MacGregor	
		US-5,306,286	04/26/1994	Stack et al.	
		US-5,266,073	11/30/1993	Wall	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document: Country Code[3] - Number[4] - Kind Code[5] (If known)	Publication Date (MM-DD-YYYY)	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
		WO 95/09586	04/13/1995	Emory University		☐

Examiner Signature		Date Considered	

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[5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible.

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SHEET 2 of 2

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Filing Date	9/5/2000
First Named Inventor	Leonard Pinchuk et al.
Art Unit	3731
Examiner Name	Michael H. Thaler
Attorney Docket No.	BSI-430US8

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]
		Copy of European Search Report for Application No. EP 03 07 5624 dated June 18, 2004	☐
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Applicant:	Leonard Pinchuk et al.
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TC/A.U.:	3731
Examiner:	Michael H. Thaler

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Sir:

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In accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

Please note that references WO 95/09586 and the article from G.J. Wilson have already been previously submitted in an IDS.

More than three months have elapsed since the filing of the above-referenced application and a first (non-Final) Official Action has been received. No Final Action or Notice of Allowance has yet been received and it is presumed that none has yet been mailed. Accordingly, as more specifically indicated below, a statement as required by 37 C.F.R. § 1.97(c) is provided herewith.

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Respectfully submitted,

Jonathan H. Spadt, Reg. No. 45,122
Attorney for Applicants

JHS/dhm

Enclosures: PTO Form 1449
(2) References
Search Report
Transmittal Form

Dated: August 6, 2004

☒ P.O. Box 980
Valley Forge, PA 19482
(610) 407-0700

The Commissioner for Patents is hereby authorized to charge payment to Deposit Account No. 18-0350 of any fees associated with this communication.

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August 6, 2004

Denise Morgan

(AW 08/03)

Substitute for Form 1449A/PTO

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		EP 0 722 701 A1	07/24/1996	Cordis Europa N.V.		☐
		WO 95/21592	08/17/1995	Mintec, Inc.		

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Approved for use through 7/31/2006. OMB 0651-0031

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Application Number	09/657,041
Filing Date	9/5/2000
First Named Inventor	Leonard Pinchuk et al.
Art Unit	3731
Examiner Name	Michael H. Thaler
Attorney Docket No.	BSI-430US8

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]
		Copy of European Search Report for Application No. EP 03 00 5616 dated June 3, 2004	☐
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Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

[1]Applicant's unique citation designation number (optional).

[2]Applicant is to place a check mark here if English language translation is attached.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No:	09/657,041
Applicant:	Leonard Pinchuk et al.
Filed:	9/5/2000
Title:	Expandable Supportive Branched Endoluminal Grafts
T.C./A.U.:	3731
Examiner:	Michael H. Thaler

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98 and to the duty of disclosure set forth in 37 C.F.R. § 1.56, the Examiner is requested to consider copending Application No. **10/692,886**.

In the present application, applicants copied claims from the U.S. Patent No. 6,576,009 issued to Ryan et al. on June 10, 2003. The '009 patent issued from Application No. 09/502,942, filed on February 11, 2000 and published on October 24, 2002 as U.S. Patent Application Publication No. 2002/0156521. Claims 54-61 currently pending in Application No. 10/692,886 are substantially the same as claims of the '521 Patent Application Publication.

On April 28, 2003, the Ryan et al. applicants filed Application No. 10/423,905. The '905 application was published as Patent Application Publication No. 2003/0195614 on October 16, 2003. The claims in the '614 Patent Application Publication are substantially the same as the claims in the '521 Patent application Publication. On October 15, 2004, claims substantially the same as claims in the '614 Patent Application Publication were added to U.S. Application Serial No. 10/692,886 in a Fourth Preliminary Amendment to the '886 application. More specifically, claims 85-92 are currently pending in the '856 application and are substantially the same as claims in the '614 Patent Application Publication.

Even though claims 85-92 in the '886 application are substantially the same as claims 54-61 in that same application, claims 85-92 were added in an abundance of caution in case the copying was required by 35 U.S.C. § 135(b)(2).

Although the information submitted herewith may be "material" to the Examiner's consideration of the subject application, this submission is not intended to constitute an admission that such information is "prior art" as to the claimed invention.

In accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

More than three months have elapsed since the filing of the above-referenced application and a first (non-Final) Official Action has been received. No Final Action or Notice of Allowance has yet been received and it is presumed that none has yet been mailed. Accordingly, the required fee set forth in 37 C.F.R. § 1.17(p) is provided herewith.

Respectfully submitted,

Jonathan H. Spadt, Reg. No. 45,122
Attorney for Applicants

JHS/dhm

Enclosures: Transmittal Form
Fee Transmittal
Credit Card Payment Form

Dated: October 25, 2004

☒ P.O. Box 980
Valley Forge, PA 19482
(610) 407-0700

The Commissioner for Patents is hereby authorized to charge payment to Deposit Account No. 18-0350 of any fees associated with this communication.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, with sufficient postage, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on:

October 25, 2004

PTO/SB/51 (10-00)
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SUPPLEMENTAL REISSUE APPLICATION DECLARATION BY THE INVENTOR

Docket Number (Optional)
BSI-430US8

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is described and claimed in patent number 5,855,598 granted January 5, 1999 , and for which a reissue patent is sought on the invention entitled EXPANDABLE SUPPORTIVE BRANCHED ENDOLUMINAL GRAFTS,

the specification of which

☐ is attached hereto.

☒ was filed on September 5, 2000 as reissue application number 09/657,041
and was amended on _____ .
(If applicable)

I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.

I verily believe the original patent to be wholly or partly inoperative or invalid, for the reasons described below. (Check all boxes that apply.)

☐ by reason of a defective specification or drawing.

☒ by reason of the patentee claiming less than he had the right to claim in the patent.

☐ by reason of other errors.

At least one error upon which reissue is based is described below. If the reissue is a broadening reissue, such must be stated with an explanation as to the nature of the broadening:

This reissue is a broadening reissue. At least the following errors exist as a basis for this reissue:

1. Originally the claims required that the liner of the trunk component have both a generally cylindrical upper body portion and a generally cylindrical lower body portion. The error is that this is unduly narrow in that the liner need only have a generally cylindrical body portion and two leg portions.

2. Originally the claims required several steps to make a supportive graft, including inserting and inflating a liner. The error here is that this is unduly narrow in that the specification also teaches simply a method of forming a supporting component comprising the steps of forming a support component and crimping at least one portion to provide a multiple-lumen portion.

PTO/SB/51 (10-00)
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(REISSUE APPLICATION DECLARATION BY THE INVENTOR, page 2)

Docket Number (Optional)
BSI-430US8

All errors corrected in this reissue application arose without any deceptive intention on the part of the applicant. As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

Name(s)	Registration Number
Jonathan H. Spadt	45,122
Paul F. Prestia	23,031
(additional listed on attached sheet)	

Correspondence Address: Direct all communications about the application to:

☒ Customer Number 23122 → Place Customer Number Bar Code Label here

OR *Type Customer Number here*

☐ Firm or Individual Name					
Address					
Address					
City		State		ZIP	
Country					
Telephone		Fax			

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine and imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this declaration is directed.

Full name of sole or first inventor (given name, family name)
Leonard Pinchuk

Inventor's signature

Residence Miami, Florida	Date
Mailing Address 13704 SW 92 Court Miami, Florida 33176	Citizenship USA

Full name of second joint inventor (given name, family name)
Rysler Alcime

Inventor's signature	Date
Residence Miami, Florida	Citizenship USA

Mailing Address 925 N.E. 122th Street
Miami, Florida 33161

Full name of third joint inventor (given name, family name)
Yasushi Kato

Inventor's signature	Date
Residence Pembroke Pines, Florida 33029	Citizenship USA

Mailing Address
311 S.W. 187th Avenue
Pembroke Pines, Florida 33029

☐ Additional joint inventors are named on separately numbered sheets attached hereto.